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In The
Supreme Court of the United States

AMERICAN CHIROPRACTIC ASSOCIATION, INCORPORATED, a non-profit corporation, *et al.*,
Petitioners,

v.

TRIGON HEALTHCARE, INCORPORATED, *et al.*,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

George P. McAndrews
Counsel of Record
Steven J. Hampton
Patrick J. Arnold, Jr.
Sharon Hwang
James P. Murphy
Peter J. McAndrews
Ronald A. Dicerbo
MCANDREWS, HELD & MALLOY, LTD.
34th Floor
500 West Madison Street
Chicago, IL 60661
(312) 775-8000

Thomas R. Daly
ODIN, FELDMAN, & PITTLEMAN, P.C.
9032 Lee Highway
Suite 1100
Fairfax, VA 22031
(703) 218-2100

William G. Shields
THORSEN & SCHER
3810 Augusta Ave.
Richmond, VA 23230
(804) 359-3000

Counsel for Petitioners

THE LEX GROUP ♦ 1108 East Main Street ♦ Suite 1400 ♦ Richmond, Virginia 23219
(804) 644-4419 ♦ (800) 856-4419 ♦ Fax: (804) 644-3660 ♦ www.thelexgroup.com

QUESTIONS PRESENTED

From 1962 and officially through 1980, the American Medical Association conducted a "lengthy, systematic, successful, and unlawful" campaign to eradicate chiropractic as a profession. *See Wilk v. American Medical Ass'n*, 895 F.2d 352, 367 (7th Cir. 1990), *cert. denied*, 498 U.S. 982, 111 S. Ct. 513 (1990). An ethics ban on all referrals between medical doctors and chiropractors was the centerpiece of that illegal boycott by the AMA. This case represents the remnants of the illegal medical physician boycott scattered by the injunction against the AMA in the *Wilk* case.

(1) Is Sherman Act § 1 rendered non-existent by the Fourth Circuit's marked departure from and overreaching application of this Court's seminal *Copperweld* decision, and three Circuit Courts' implementation of that decision, on intra-corporate immunity, where it holds that medical doctors representing Virginia's professional medical associations and the medical physician employees of Virginia's largest healthcare insurance company, who combined to jointly issue fraudulent lower back pain treatment and industry referral standards, are a single entity which is incapable of conspiring because all of the representatives of the state's medical societies are "agents" of the insurance company?

(2) Did the Fourth Circuit violate longstanding antitrust jurisprudence when it held, contrary to decisions of the Sixth, Eighth and Eleventh Circuits, that a health insurance company and its medical doctor employees and medical doctors appointed by and representing competitive state medical doctor associations, who agreed to adopt fraudulent industry-wide referral treatment and reimbursement guidelines to limit the flow of insurance monies to chiropractors, were incapable of conspiring or combining because the medical doctor association representatives became "agents" of the insurance company?

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

CORPORATE PLAINTIFF-APPELLANTS

(1) American Chiropractic Association, Inc.

The American Chiropractic Association, Inc., is a trade association; there is no parent or publicly held company owning 10% or more of the stock.

(2) Virginia Chiropractic Association, Inc.

The Virginia Chiropractic Association is a trade association; there is no parent or publicly held company owning 10% or more of the stock.

INDIVIDUAL PLAINTIFF-APPELLANTS

George W. Chirkinian, D.C.
3509 Jefferson Davis Highway
Richmond, VA 23234
(804) 233-9244

Douglas M. Cox, D.C.
1006 East Market Street
Charlottesville, VA 22902
(434) 293-6165

William R. Thesier, D.C.
Thesier Chiropractic Clinic
240 Mustang Trail
Suite 3
Virginia Beach, VA 23452
(757) 486-3222

John C. Willis, D.C.
Willis Chiropractic Offices
305 Allegheny Street
P.O. Box 1045
Richlands, VA 24641
(276) 963-0395

Jerry R. Willis, D.C.
Willis Chiropractic Center
570 E. Main Street
Wytheville, VA 23842
(276) 228-3883

Douglas F. Ambrose, D.C.
601 N. Courthouse Road
Suite 1
Richmond, VA 23236
(804) 897-6130

George B. McClelland, D.C.
McClelland Chiropractic Clinic
155 Walters Drive
Christiansburg, VA 24073
(540) 382-3333

James M. Porter, D.C.
Porter Chiropractic Clinic
P.O. Box 1423
Wytheville, VA 24382
(276) 228-5793

Larry L. Stine, D.C.
Stine Chiropractic Clinic
117 Redwood Drive
Fredericksburg, VA 22408
(540) 898-4100

Wendy Holden Willis, D.C.
Willis Chiropractic
570 E. Main Street
Wytheville, VA 23842
(276) 228-3883

Steven W. Yates, D.C.
Gloucester Chiropractic Center
P.O. Box 632
Gloucester Point, VA 23062
(804) 642-6106

Ms. Sara Elizabeth Allen
6036 Deerwater Court
Richmond, VA 23237
(804) 271-2316

Ms. Lana Kay Ball
Route 1, Box 157B
Cedar Bluff, VA 24609
(276) 963-2120

Ms. Margaret Byrne
23 Morewood Place
Palmyra, VA 22963
(434) 589-1827

Mr. Roger Dalton
P.O. Box 981
Rural Retreat, VA 24368
(276) 686-9178

Ms. Mary Sue Dean
P.O. Box 588
Cedar Bluff, VA 24609
(276) 964-4942

Mr. Harvie Lee French, Jr.
Route 2, Box 287
Bland, VA 24315
(276) 928-1792

Ms. Patricia Herman
5905 Country Walk Road
Midlothian, VA 23112
(804) 739-3853

Ms. Cindy Linkenhoker
4401 Woodberry Cresent
Suffolk, VA 23435
(757) 393-8592

Ms. Sandra Phillipi
1695 W. Main Street
Wytheville, VA 24382
(804) 553-8684

Ms. Darlene Requizo
310 San Roman Drive
Chesapeake, VA 23322
(757) 494-7520

Mr. David Russotto
5028 Martin's Point Road
Kitty Hawk, NC 27949
(252) 207-1883

Ms. Gloria Jean Smith
P.O. Box 105
Cedar Bluff, VA 24609
(276) 880-3115

Mr. Lynn D. Wagner
14208 Spring Gate Road
Midlothian, VA 23112
(804) 763-0044

Ms. Patricia Whittington
233 Burnett Street
Richlands, VA 24641
(276) 964-4637

Mr. Dale Duke Yontz
430 East Monroe Street
Wytheville, VA 24382
(276) 228-6777

DEFENDANTS-APPELLEES

Trigon Healthcare, Inc.
Trigon Health & Life Co.
Trigon Insurance Co.
Trigon Administrators, Inc.
Mid-South Insurance Company
Anthem, Inc.

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OPINIONS BELOW

The Fourth Circuit Decision, from which this Petition comes, is reported at 367 F.3d 212 (4th Cir. 2004), and is reprinted at App. 1a - 42a. The June 2, 2004 Fourth Circuit denial of the Petition For Rehearing and Petition For Rehearing *En Banc* is not reported in the official reporters, and is reprinted at App. 60a - 61a. The April 25, 2003 summary judgment decision of the District Court for the Western District of Virginia, is reported at 258 F. Supp. 2d 461 (W.D. Va. 2003), and is reprinted at App. 43a - 59a.

JURISDICTIONAL STATEMENT

The Fourth Circuit denied the Petition For Rehearing en banc on June 2, 2004. This Petition For Writ of Certiorari is timely because it has been filed within 90 days of June 2, 2004. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

This case involves the interpretation of and application of Section One of the Sherman Act, 15 U.S.C. § 1, and Section Four of the Clayton Act, 15 U.S.C. § 15(a). The relevant part of Sherman Act Section One provides:

> Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.

15 U.S.C. § 1 (2004). The relevant part of Section Four, subsection (a) of the Clayton Act provides:

> a) Amount of recovery; prejudgment interest
>
> Except as provided in subsection (b) of this section, any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent,

> without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee.

15 U.S.C. § 15(a) (2004).

STATEMENT OF THE CASE

The Fourth Circuit affirmed the District Court's summary judgment ruling in this antitrust case that representatives of competitive state medical doctor associations - comprising more than 90% of the medical doctors in Virginia -- became "corporate agents" of Virginia's largest insurance company, where they collaborated to create, adopt and endorse state-wide back pain treatment, referral and insurance-reimbursement guidelines, which created industry standards affecting reimbursement based upon how medical doctors refer back pain patients for treatment for insurance purposes, and which guidelines fraudulently excluded doctors of chiropractic.

The plaintiffs, the American Chiropractic Association, the Virginia Chiropractic Association, and individual chiropractors and patients, believe the lower court rulings are legal error because separate distinct entities combined to restrain trade and directly harm chiropractors -- direct competitors of the medical doctors -- and their patients and potential patients.

The facts of this case were not written on a clean slate. Medical doctors, and specifically the American Medical Association ("the AMA"), its 1990 state, county and local affiliated societies, and numerous other medical specialty groups, sought for many, many years to eradicate chiropractic as a profession.

In 1962, the AMA undertook a "lengthy, systematic, successful, and unlawful" campaign to eradicate chiropractic as a profession. *See Wilk v. American Medical*

Ass'n, 895 F.2d 352, 367 (7th Cir. 1990), *cert. denied*, 498 U.S. 982, 111 S. Ct. 513 (1990). App. 393a - 448a. The illegal conduct officially lasted until 1980, but the effects of that unlawful campaign by the AMA still linger. *See Wilk*, 895 F.2d at 357 (noting that the District Court found that "chiropractors continued to suffer [after the illegal boycott officially ended] because the boycott's negative effects (namely, inhibiting AMA members' individual decision-making in their relationships with chiropractors) still remained.")). A primary focus of the illegal boycott was to prevent all medical referrals to or from chiropractic as unethical. *Id.*, at 372.

Subsequently, representative agents appointed by almost every medical doctor association in Virginia, whose membership is comprised of nearly all of Virginia's medical doctors, combined with Trigon Healthcare, Inc., by far Virginia's largest private health insurer (a Blue Cross/Blue Shield licensee), at the request of Trigon, to form what was deemed a "Managed Care Advisory Panel" ("MCAP"). As the Fourth Circuit acknowledged, "[Plaintiff] American Chiropractic is undoubtedly correct that medical doctors and insurance companies do not, generally speaking, share a unity of interest." Fourth Circuit Decision, at 14 (App. 17a).

The MCAP members combined and agreed, incorrectly, fraudulently, and contrary to a thorough, unbiased and extensive U.S. Government study by the Agency for Health Care Policy and Research ("AHCPR"), to disseminate false back pain referral and treatment guidelines to 90% of Virginia's medical doctors. The industry standard guidelines created by the MCAP were fraudulent because they failed to acknowledge or recommend referral for chiropractic spinal manipulation for back pain. Chiropractic spinal manipulation is offered almost exclusively by chiropractors and was proven in the AHCPR study to be as or more effective a medical modality as, and more cost-effective than, the services offered exclusively by medical doctors.

What emerged from the conspiracy of the MCAP was a historical and scientific distortion of the content of the AHCPR study. According to Dr. Scott Haldeman, a world renowned authority and a member of the AHCPR panel:

> By omitting the AHCPR's definitions of manipulation, Trigon and its Managed Care Advisory Panel materially altered the recommendations of the AHCPR. That alteration created a Trigon guideline that did not recommend the manipulation that is provided primarily by doctors of chiropractic as did the AHCPR Guidelines. A point that became evident from the AHCPR guidelines was that manipulation was the only treatment approach that required a medical physician, in most instances, to make a referral of a patient with uncomplicated low back pain. The inevitable, and obviously intended, consequence of Trigon's and the Managed Care Advisory Panel's alteration of the AHCPR guideline, is to deprive patients of the benefit from spinal manipulation as practiced by doctors of chiropractic, and to deprive doctors of chiropractic of the opportunity to treat those patients.

App. 212a.

Trigon and the MCAP then officially "approved" and adopted their false referral guideline, and disseminated it to every medical doctor in Virginia in Trigon's network, thereby establishing their individual referral policies and deterring the individual medical doctors from referring patients with lower back pain to chiropractors. The false referral guideline adopted, approved and endorsed by the medical doctors on the MCAP and the Trigon insurance company comprised an anticompetitive "contract, combination or conspiracy in restraint of trade," which favored and benefited the medical doctors, and the medical organizations and members they represented, who

combined with Trigon to disseminate it, to the detriment of chiropractic and their patients.

The Fourth Circuit Court of Appeals, affirming the District Court summary judgment below, held that the medical doctors, who were appointed as representatives of the Virginia medical societies, became corporate agents of the insurance company solely by virtue of their combination on a "panel" and, therefore, that these otherwise independent actors became a single entity which could not as a matter of law combine or conspire. App. 47a – 53a; App. 17a – 18a.

The Fourth Circuit holding directly conflicts with and undermines this Court's holding in *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 104 S. Ct. 2731 (1984) (App. 305a – 362a), and other decisions of this Court, by holding that admittedly separate and independent economic actors became a single entity, as agents of one another, as a matter of law merely because they embarked on a common scheme. This holding renders void any concept of a conspiracy or combination.

The Fourth Circuit holding also directly conflicts with and undermines this Court's holding in *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 108 S. Ct. 1931 (1988) (App. 363a – 392a), by holding that an industry standard-setting combination of separate economic entities is never subject to antitrust scrutiny under Section One of the Sherman Act. The Fourth Circuit holding also directly conflicts with holdings of the Sixth Circuit, the Eighth Circuit, and the Eleventh Circuit, as set forth *infra*.

The Fourth Circuit holding has far-reaching and dire effects on the law of antitrust and on healthcare in the United States. The holding is not limited to the facts of the case. The result of the Fourth Circuit Decision is that medical associations and insurance companies can legally combine and conspire to expressly set industry standards that limit patient referrals, and thus insurance reimbursement and healthcare treatment, to any selected healthcare providers (*i.e.*, expressly restrain the healthcare

trade) to the detriment of patients and other competing healthcare providers. This result is at odds with the very analogous conspiracy found by the Seventh Circuit in the *Wilk* case, *supra* pp. 2-3, to be a gross antitrust violation, and will perpetuate the long-lasting effects of that illegal conspiracy.

BACKGROUND OF THE CASE

The plaintiffs in this case are The American Chiropractic Association, comprised of doctors of chiropractic throughout the United States, the Virginia Chiropractic Association, and individual doctors of chiropractic, and patients of doctors of chiropractic. The defendants are Trigon Healthcare, Inc. ("Trigon") and its healthcare subsidiaries that do business as Trigon in Virginia.

This case was filed in 2000, but the anticompetitive conduct by medical doctors against chiropractic dates back to at least 1962 when the AMA formed its now-infamous "Committee on Quackery" to "eliminate chiropractic" as a medical profession. *Wilk*, 895 F.2d at 356. This historical conspiratorial and unlawful conduct by the AMA and its co-conspirators against chiropractic should be understood as a backdrop to this antitrust action involving over 90% of the medical doctors in Virginia. App. 393a - 448a.

This case, and the Decision of the Fourth Circuit ("Fourth Circuit Decision"), has potentially profound financial and healthcare ramifications within the Fourth Circuit and potentially throughout the United States. Perhaps most importantly, the outcome of this case will have profound effects on patients with severe musculo-skeletal afflictions, and especially back pain, who may not otherwise have an informed choice of medical care or be financially able to pay their portion for the preferred treatment for lower back pain.

The potential effect is enormous. Studies have found that 100% of the population will be afflicted with back pain at some time during their lifetime. App. 807a; 1045a. Moreover, healthcare in the United States comprises a $1.6

trillion industry. App. 1077a. In 2002, the most recent year for which government data are available, national spending for healthcare was broken down and summarized by the Center For Medicare and Medicaid Services (an agency of the U.S. Department of Health and Human Services), as follows:

> In 2002, national health expenditures totaled $1,553,009 Million [(or $1.55 trillion)].
>
> * * *
>
> Private health insurance expenditures totaled $549,572 Million [$550 billion] (35% of total expenditures, 65% of private expenditures).

App. 1077a (The entire report (file nhe02.zip) can be found at http://www.cms.hhs.gov/statistics/nhe/#download)). Thus, vast amounts of money are spent every year on private health care, mostly funded by private healthcare insurers, like Trigon.

In 1994, the U.S. Government Department of Health and Human Services Agency for Health Care Policy and Research ("AHCPR") issued a non-partisan, unbiased 170-page study entitled "Acute Low Back Pain in Adults," along with an accompanying 30-page "Quick Reference Guide for Clinicians" entitled "Acute Low Back Problems in Adults: Assessment and Treatment." App. 798a – 1040a, 1041a – 1071a. The study was conducted by a multidisciplinary panel comprised of 12 medical physician experts, and other healthcare professionals and consumer representatives, who were brought together by the Agency for Health Care Policy and Research to perform an evidence-based analysis of all research trials on all treatment approaches to acute low back pain in adults. App. 798a - 809a. Abstracts of over 10,000 research papers were reviewed, and almost 4,000 articles were retrieved. App. 819a – 822a.

The AHCPR study took nearly two years to complete. It included a series of specific recommendations for low back pain in the "Quick Reference Guide for Clinicians" attached thereto which was available free for all who wished to copy

and distribute it. App. 802a - 804a; 1041a-71a. Recommendations were for acetaminophen and NSAIDs (Non-Steroidal Anti-Inflammatory Drugs), as well as manipulation in place of medication, or a short trial of manipulation combined with NSAIDs. App. 1055a. Importantly, the AHCPR study specifically defined spinal manipulation as the type of manipulation used by all chiropractors and some osteopaths, rather than other manipulation techniques. App. 859a.

The Associated Press and major newspapers throughout the country immediately recognized that the AHCPR study, which was published on December 8, 1994, was a boon to chiropractors and a potential setback for medical doctors. App. 1072a - 76a. The responsible medical world still looked at the 1994 AHCPR study as a boon to chiropractic in 1998 as indicated in the *Annals of Internal Medicine*, July 1998, published jointly by the American College of Physicians and the American Society of Internal Medicine:

> The Agency for Health Care Policy and Research (AHCPR) recently made history when it concluded that spinal manipulative therapy is the most effective and cost-effective treatment for acute low back pain ... Perhaps most significantly, the guidelines state that unlike nonsurgical interventions, spinal manipulation offers both pain relief and functional improvement.

App. 1040a-i (underlining added)).

In response to the AHCPR study, Trigon and the "Managed Care Advisory Panel" sought to develop lower back pain referral and treatment standards for the 90% of the medical doctors in Virginia that provide Trigon-covered healthcare. App. 1095a - 1104a. Dr. Larry Colley, Vice President of Medical Policy at Trigon, described the MCAP as follows:

> Trigon's internal review process included consultation with, **and approval by representatives appointed by** the Virginia chapter of the American

> Academy of Pediatrics, the Virginia chapter of the American Academy of Family Physicians, the Virginia Society of Internal Medicine, the Virginia chapter of the American College of Physicians, the Virginia chapter of the American College of Surgeons, the Virginia Obstetrical and Gynecological Society, the Medical Society of Virginia, the University of Virginia School of Medicine, Eastern Virginia Medical School and the Medical College of Virginia.

App. 1103a – 04a (emphasis added). The MCAP also had six Trigon employees, four of them medical doctors. App. 1095a. Notably, the MCAP did not include a single chiropractor or chiropractic representative, or any other non-medical doctor healthcare provider. App. 1095a.

The MCAP ultimately adopted and endorsed, and Trigon approved and disseminated to virtually every medical doctor in Virginia, a fraudulent referral and treatment guideline for lower back pain. The minutes from the MCAP adoption meeting show the direct conspiracy:

> **TOPIC**: Approval of Practice Guidelines from Regional Committees 1. Low Back Pain .....
>
> **DISCUSSION**: Dr. Hattwick: we need to go over these one by one – are these referral guidelines?
>
> Dr. Colley: yes, they are referral guidelines.
>
> Dr. Hattwick: we should emphasize that they are referral guidelines, if they are.
>
> Dr. Grinnan: the guidelines are a baseline of what a primary care physician should manage in these categories, and we are reviewing them regionally.
>
> Dr. Hattwick: operationally, these are a mixture of management and referral guidelines.
>
> * * *
>
> **ACTION**: Unanimously adopted by Committee.

App. 1095a - 1102a (underlining added).

The Low Back Pain referral guideline that was adopted by Trigon and the MCAP was false, contrary to the conclusion reached by the extensive and thorough study of the AHCPR, and directly benefited medical doctors to the detriment of both chiropractors and, most importantly, back pain patients. App. 1094a-i to 1094a-x; 1137a; 210a-212a. This referral guideline was fraudulent because it excluded referrals to chiropractors by all Trigon-participating medical doctors -- 90% of the medical doctors in Virginia -- or reference to the chiropractic type of spinal manipulation, and it resulted in insurance reimbursement for treatment to only untrained medical doctors, despite the conclusion of the AHCPR study that chiropractic spinal manipulation was a more effective treatment. App. 210a - 17a. These exclusions denied back pain patients superior medical care, harmed chiropractors and their patients financially, and illegally restrained trade.

The plaintiffs presented uncontroverted evidence to the District Court, and to the Fourth Circuit, that the resulting exclusion of referrals to Virginia chiropractors alone resulted in over $100,942,391 in lost fees from 1996 to 2001. As Dr. Schifrin, Ph.D. testified:

> To this point three losses of income to chiropractors have been identified. These losses, and the measured magnitude of each, are:
>
> Losses from annual caps on patient chiropractic benefits: unspecified but possibly large.
>
> Losses from underpayments caused by discounting non-CMT code treatments and leveling CMT code treatments: $35,450,575.
>
> Losses from deterred demand: $65,492,356.
>
> Total calculable losses to Virginia chiropractors, 1996-2001: $100,942,391.

App. 1137a (Expert Witness Statement of Leonard G. Schifrin, Ph. D.); *see also* App. 156a – 209a (Rand Corporation concluding that chiropractors offer 90% of the spinal manipulation services provided in the United States)).

The Fourth Circuit disregarded nearly all of this. Despite the fact that medical doctors and insurance companies are admittedly independent economic actors, despite the fact that plaintiffs proffered direct and compelling evidence that the separate entities did in fact agree to false treatment guidelines which favor the medical doctors to the detriment of chiropractors as their direct competitors, and despite the fact that the Plaintiffs submitted evidence of substantial economic harm, the Fourth Circuit incorrectly applied the "intracorporate immunity" doctrine and summarily stated,

> American Chiropractic is undoubtedly correct that medical doctors and insurance companies do not, generally speaking, share a unity of interest. That, however, is not the correct inquiry in cases applying the intracorporate immunity doctrine. Instead, we look to whether the medical doctors, in their role as members of the MCAP, share a unity of interest with Trigon that makes them corporate agents of Trigon. We believe that they do.
>
> * * *
>
> Thus, we agree with the district court that Trigon lacked the capacity to conspire, within the meaning of § 1, with its corporate agent, the MCAP or its members.

Fourth Circuit Decision, at 14 App. 17a. That ruling destroys well-established antitrust jurisprudence.

If any healthcare insurance company can combine with any preferred group of healthcare service providers to set medical standards that fraudulently exclude competing healthcare suppliers and harm the excluded suppliers and

patients, Section One of the Sherman Act is effectively revoked.

REASONS FOR GRANTING CERTIORARI

I. The Writ Should Be Granted Because The Fourth Circuit Decision Directly Conflicts With And Guts This Court's Holdings in *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 104 S. Ct. 2731 (1984), and *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 108 S. Ct. 1931 (1988)

The Decision of the Fourth Circuit is contrary to more than 100 years of Supreme Court antitrust precedent, and will render meaningless Section One within the Fourth Judicial Circuit.

In 1984, this Court solidified antitrust law when it decided *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 104 S. Ct. 2731 (1984). App. 305a – 362a. In clarifying "[t]he distinction between unilateral and concerted conduct ... for a proper understanding of the terms 'contract, combination ... or conspiracy' in § 1" of the Sherman Act, this Court stated:

> A § 1 agreement may be found when the conspirators had a unity of purpose or a common design and understanding, or a meeting of minds in an unlawful arrangement.

Copperweld, 467 U.S. at 771, 104 S. Ct. at 2742. Ultimately, this Court held that a single corporation is incapable of conspiring, vis-à-vis Sherman Act § 1, with its wholly-owned subsidiary because each entity is not independent and, indeed, because such entities "always have a unity of purpose or a common design." *Id.* (emphasis added). This became known as the "intracorporate immunity" doctrine.

The Fourth Circuit Decision at issue directly conflicts with that clear and express *Copperweld* holding, and inexplicably expands the intracorporate immunity doctrine. The Fourth Circuit first stated:

> [Plaintiff] is undoubtedly correct that medical doctors and insurance companies [the actors comprising the MCAP] do not, generally speaking, share a unity of interest.

App. 17a. Despite this admitted and obvious non-unity of interest of the separate actors in this case, the Fourth Circuit went on to wrongly conclude:

> The individual doctors [who were appointed as representatives of the medical associations], in their role as members of MCAP, shared the same interest as Trigon .... The MCAP is without question a corporate agent of Trigon.

Id. That was the entire basis of the Fourth Circuit decision on the issue of "unilateral conduct" -- that the medical doctors representing every major medical doctor association in Virginia became a "agents" of the defendant insurance company. It directly conflicts with *Copperweld.*

In 1988, this Court again set a clear boundary around exclusionary antitrust activity. In *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 108 S. Ct. 1931 (1988), this Court held that when an association, like the MCAP, combines to set standards in an industry, like the Trigon-adopted back pain referral and treatment guidelines, the standards set by the combination has a "serious potential for anticompetitive harm." 486 U.S. at 505, 108 S. Ct. at 1937. App. 363a - 392a.

> In *Allied Tube*, a group of manufacturers of building materials, which included makers of steel conduit, were members of the National Fire Protection Association ("NFPA"), an organization which developed and updated a model electric code, mainly for use by state and local governments in setting standards for construction. The code was highly influential. Many local governments adopted it virtually verbatim, and many insurance companies refused to insure buildings that did not meet the

> code's requirements. Then, Indian Head, a relatively small firm, developed an alternative to steel conduit made of polyvinyl chloride. This plastic conduit was cheaper to make and cheaper and easier to install. Further, since it was made of a non-conductor, it was less susceptible to short circuits. When Indian Head attempted to have the plastic conduit approved in the NFPA's model code, the defendant makers of steel conduit "packed" the relevant NFPA meeting with their own agents and employees. Allied alone sent 155 people to the meeting, most of whom had no knowledge about the merits of plastic conduit, and the new conduit was disapproved by a vote of 394 to 390.

H. Hovenkamp, *Exclusive Joint Ventures And Antitrust Policy*, 1995 COLUM. BUS. L. REV. 1, 27-28 (footnotes omitted) . App. 449a - 618a. The Supreme Court affirmed the holding below that this conduct by an association and its members to set exclusionary industry guidelines violated Section One of the Sherman Act. *Allied Tube*, 486 U.S. at 508-10, 108 S. Ct. at 1941-42.

The Fourth Circuit disregarded the clear precedent of the Supreme Court, and held that a combination of competitors was incapable of violating the antitrust laws. The cursory factual and logical leap by the Fourth Circuit in the case at bar is 100% at odds with the clear *Copperweld, Allied Tube* and other Supreme Court decisions. Healthcare providers (like medical doctors, doctors of chiropractic, etc.) are necessarily separate and distinct economic entities vis-à-vis healthcare insurers. Healthcare providers supply healthcare services, and insurers purchase healthcare services. Their economic interests in the marketplace are distinct. *See* Fourth Circuit Decision, at 14 (App. 17a).

When the Fourth Circuit declared that, by sole virtue of their having formed a "panel," the appointed representatives of 90% of the medical doctors in Virginia became "agents" of Virginia's largest insurance company, and that these independent market participants now

"shared the same interest" and could not legally "combine" for purposes of Sherman Act, Section One, the Fourth Circuit emasculated Section One, and gutted *Copperweld* and *Allied Tube*, and their progeny. Holding, as the Fourth Circuit did, that whenever independent actors combine for a "shared interest" the actors are necessarily immune from a "contract, combination, or conspiracy," is antithetical. Instead of being exempt from antitrust scrutiny, such combinations demand heightened scrutiny, especially where the healthcare providers collaborating with the insurance companies are limited to only medical doctors, to the exclusion of all other healthcare providers, including competing healthcare providers, like chiropractors. The Fourth Circuit got it exactly backward.

Congress and the Supreme Court, since the inception of the antitrust laws, have consistently stated that a combining of independent market participants demands heightened scrutiny because of its potential for consumer harm.

> The reason Congress treated concerted behavior more strictly than unilateral behavior is readily appreciated. Concerted activity inherently is fraught with anticompetitive risk. It deprives the marketplace of the independent centers of decisionmaking that competition assumes and demands. In any conspiracy, two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit. This not only reduces the diverse directions in which economic power is aimed but suddenly increases the economic power moving in one particular direction. Of course, such mergings of resources may well lead to efficiencies that benefit consumers, but their anticompetitive potential is sufficient to warrant scrutiny even in the absence of incipient monopoly.

Copperweld, 467 U.S. at 768-69, 104 S. Ct. at 2740; *see also Allied Tube*, 486 U.S. at 500, 108 S. Ct. at 1937 ("There is no

doubt that the members of such associations often have economic incentives to restrain competition and that the product standards set by such [standard-setting trade] associations have a serious potential for anticompetitive harm.").

Moreover, the actual "combination, contract or conspiracy" need not be nefarious or even express to constitute such "contract, combination or conspiracy" for antitrust purposes. Any "meeting of the minds" between independent economic actors that unlawfully restrains trade is subject to heightened scrutiny. Thus, the Fourth's Circuit's statement, that Plaintiffs did not present sufficient direct evidence of a conspiracy, is both factually wrong, and legal error. App. 19a –22a. As was shown, the independent medical doctor associations and Trigon unanimously agreed to the fraudulent "referral guidelines." The minutes from the MCAP adoption meeting show the direct conspiracy. *Supra*, p. 9. Thus, the Fourth Circuit statement, that "At most, the MCAP meeting shows contact between two independent economic actors," is inexplicable and wrong. *See* Fourth Circuit Decision, at p. 17. App. 21a.

The Fourth Circuit noted that the MCAP approved guidelines prepared by Trigon and couldn't require Trigon to revise those guidelines. App. 17a – 18a. This is entirely irrelevant.

> It is elementary that an unlawful conspiracy may be and often is formed without simultaneous action or agreement on the part of the conspirators. ... Acceptance by competitors, without previous agreement, of an invitation to participate in a plan, the necessary consequence of which, if carried out, is restraint of interstate commerce, is sufficient to establish an unlawful conspiracy under the Sherman Act.

Interstate Circuit, Inc. v. United States, 306 U.S. 208, 227, 59 S. Ct. 467, 474 (1939) (citations omitted).

As in the Beech-Nut case, there is more here than

> mere acquiescence of wholesalers in Soft-Lite's published resale price list. The wholesalers accepted Soft-Lite's proffer of a plan of distribution by cooperating in prices, limitation of sales to and approval of retail licensees. That is sufficient.
>
> * * *
>
> Whether this conspiracy and combination was achieved by agreement or by acquiescence of the wholesalers coupled with assistance in effectuating its purpose is immaterial.

United States v. *Bausch & Lomb Optical Co.*, 321 U.S. 707, 723, 64 S. Ct. 805, 813 (1944).

Holding that a combination of otherwise independent entities are necessarily immune from Section One of the Sherman Act, as the Fourth Circuit did, unravels the entire fabric of antitrust law.

> It is useless for the defendants to say they did not intend to regulate or affect interstate commerce. They intended to make the very combination and agreement which they in fact did make, and they must be held to have intended (if in such case intention is of the least importance) the necessary and direct result of their agreement.

Addyston Pipe & Steel Co. v. United States, 175 U.S. 211, 243, 20 S. Ct. 96, 108 (1899).

> It is not the form of the combination or the particular means used but the result to be achieved that the statute condemns. It is not of importance whether the means used to accomplish the unlawful objective are in themselves lawful or unlawful. Acts done to give effect to the conspiracy may be in themselves wholly innocent acts. Yet, if they are part of the sum of the acts which are relied upon to effectuate the conspiracy which the statute forbids, they come within its prohibition.

American Tobacco Co. v. United States, 328 U.S. 781, 809, 66 S. Ct. 1125, 1139 (1946); *see also United States v. General Motors Corp.*, 384 U.S. 127, 142-43, 146, 86 S. Ct. 1321, 1328-31 (1966); *United States v. Paramount Pictures*, 334 U.S. 131, 140, 68 S. Ct. 915, 921 (1948) ("It is not necessary to find an express agreement in order to find a conspiracy").

The Fourth Circuit rejected all of this precedent when it summarily held that plaintiffs failed to produce direct, or indirect, evidence of an unlawful conspiracy between Trigon and the Virginia medical associations, whose representatives were members of the MCAP. In fact, although such direct evidence was not necessary (especially on summary judgment), plaintiffs did present uncontroverted evidence of a direct combination and conspiracy that restrained trade. The MCAP brought together representatives of every major medical doctor association in Virginia with its own medical doctor employees, who expressly agreed to adopt and publish false industry standards. *See, supra.*

The documentary evidence is clear and was uncontroverted on summary judgment. Trigon proffered its fraudulent guidelines to the MCAP. App. 1095a - 1102a; 17a - 18a. The MCAP then adopted and endorsed these false guidelines. App. 1102a; 1094a-v. Trigon then disseminated these guidelines to nearly every medical doctor in Virginia, emphasizing that the guidelines were "approved and endorsed" by the MCAP. App. 1094a-v. This direct and uncontroverted evidence was simply ignored by the Fourth Circuit. That violates this Court's longstanding precedent and is legal error.

The conclusion by the Fourth Circuit is contrary to more than 100 years of Supreme Court antitrust precedent, contrary to this Court's seminal *Copperweld* and *Allied Tube* decisions, and will revoke Section One within the Fourth Judicial Circuit.

II. Review Is Warranted Because The Decision Is In Direct Conflict With Decisions Of The Sixth, Eighth, and Eleventh Circuit Courts

The Fourth Circuit Decision directly conflicts with the Sixth Circuit's holding in *Nurse Midwifery Ass'n v. Hibbett*, 918 F.2d 605 (6th Cir. 1990), *modified*, 927 F.2d 904 (1991), *cert denied*, 502 U.S. 952, 112 S. Ct. 406 (1991). In *Nurse Midwifery*, two nurse midwives and a physician who agreed to work with them brought an antitrust action against several hospitals and a physician-controlled insurance company (among others). The plaintiffs alleged in the complaint that the defendant physicians conspired to prevent nurse midwives from competing with obstetrician physicians, and to prevent the physician who assisted the nurse midwives from obtaining insurance.

Physician supervision was required at hospitals for midwife services. In furtherance of the conspiracy, the defendant physicians, *inter alia*, pressured other physicians to refuse to supervise midwives at the defendant hospitals. Further, the defendant hospitals and their medical staffs denied privileges at the hospitals to plaintiff midwives and the physicians who attempted to sponsor and supervise them. *See Nurse Midwifery*, 918 F.2d at 607-611. The District Court granted summary judgment in favor of several defendants, holding, like the Fourth Circuit Decision, that the hospitals were incapable of illegally conspiring because the doctors were "agents" of the hospital and thus they were not separate actors able to combine or conspire. *Id.*, at 614-15. The Sixth Circuit reversed that holding.

The Sixth Circuit expressly held that medical doctors on a hospital panel which made recommendations to the hospital could conspire in violation of the Sherman Act.

> The issue whether the individual members of a hospital's medical staff should be treated as agents of the hospital for antitrust purposes when making a recommendation concerning an application for staff privileges is a difficult one. ... the premise

> underlying the intracorporate conspiracy doctrine, that agents of a firm share a unity of economic purpose with the firm, does not necessarily apply when viewing the relationship between a hospital and its medical staff. The members of a medical staff are not salaried employees of the hospital but are independent medical practitioners, some in direct competition with each other and with applicants for privileges. There is certainly some danger of anticompetitive decision-making when a group of physicians recommends to the hospital that an applicant who is in competition with those physicians be denied privileges at the hospital.
>
> In contrast, the individual members of a hospital's medical staff are in many cases direct competitors with each other. .... when competing physicians are making privilege recommendations concerning another competitor, sufficient anticompetitive concerns are raised to warrant a conclusion that the members of the medical staff are not acting as agents of the hospital for purposes of applying the intracorporate conspiracy doctrine to preclude a conspiracy among staff members.

Nurse Midwifery, 918 F.2d at 614-15 (underlining added). The Fourth Circuit Decision, that medical doctors and insurance companies that combine with a common goal to advise the insurance company and set industry standards cannot combine under Section One, conflicts with this Sixth Circuit precedent.

The Fourth Circuit Decision also conflicts with the Eighth Circuit case of *Mt. Pleasant v. Associated Elect. Coop., Inc.*, 838 F.2d 268 (8th Cir. 1988). In *Mt. Pleasant*, the plaintiff city alleged that the defendant, a group of related rural electric cooperatives, violated Sections 1 and 2 of the Sherman Act. The electric cooperatives were made up of individual companies which each owned and/or operated an electricity generation and transmission grid in the

Midwest. While the Eighth Circuit ultimately held that the cooperatives were a "single entity" for purposes of the Antitrust laws, its analysis is sound, and contrary to the Fourth Circuit Decision (which offered no reasoning).

The Eighth Circuit correctly reasoned that "single entity" immunity must be based on economic reality, and not merely the form taken by the alleged conspirators. The Eighth Circuit refused to hold that combining entities that had a common interest could never "combine or conspire" for purposes of the Sherman Act. Instead, in analyzing the particular facts of the case, the Eighth Circuit stated:

> The critical distinction between this case and Topco [*United States v. Topco Assocs., Inc.*, 405 U.S. 596, 92 S. Ct. 1126 (1972)] is that here there is no evidence that any defendant ever pursued interests antithetical to those of the cooperative as a whole ....

Mt. Pleasant, 838 F.2d at 276. According to the Eighth Circuit, that lack of evidence justified the summary judgment by the District Court. The plaintiff could have defeated summary judgment, if it could

> show specific facts which present a triable issue as to whether any of the defendants has pursued interests diverse from those of the [defendant] cooperative itself.

Id., at 276. Because the plaintiff did not offer any such facts, the summary judgment below was affirmed. Here, on the other hand, the ACA proffered uncontroverted evidence that the fraudulent referral guidelines benefited the medical doctor co-conspirators to the exclusion and economic detriment of chiropractors. *See, e.g.*, App. 210a - 304a; 1105a-1153a.

The Fourth Circuit Decision also directly conflicts with the Eleventh Circuit reasoning and holding in *Bolt v. Halifax Hosp. Med. Ctr.*, 891 F.2d 810 (11th Cir. 1990). In *Bolt*, the defendant peer review committees of the defendant hospitals revoked the plaintiff medical doctor's privileges at

the hospitals. The committees asserted that the plaintiff's abrasive personality and poor professional performance warranted the revocations. The plaintiff asserted that the competing medical doctors on the committees conspired to revoke his privileges, in violation of the antitrust laws. The Eleventh Circuit held that the hospitals and the peer review committees could legally conspire for antitrust purposes, and that the peer review committees were not mere agents of the hospitals.

> To establish a violation of section 1 of the Sherman Act, a plaintiff must prove that two or more distinct entities agreed to take action against him. ... We perceive no basis, however, for holding that the members of a medical staff are legally incapable of conspiring with one another. ...
>
> Additionally, we perceive no basis for holding that a hospital is legally incapable of conspiring with the members of its medical staff. Relying on the rule that a corporation cannot conspire with its officers and directors, ... some courts have held that a hospital cannot conspire with its medical staff for purposes of section 1 liability. ... We find this analogy faulty, however. The rule for corporations is based on considerations unique to the corporate context. ... A hospital and the members of its medical staff, in contrast, are legally separate entities ....

Bolt, 891 F.2d at 817-18 [citations omitted].

The Fourth Circuit Decision flies in the face of each of these cases. The Fourth Circuit acknowledged that medical doctors and insurance companies are normally independent actors who pursue separate economic interests. *See* App. 17a. The Fourth Circuit then ignored the unrebutted evidence that the medical doctors on the MCAP were appointed as representatives of the medical associations of Virginia. App. 17a -22a; App. 1103a - 04a. The Fourth Circuit Decision ignored the admitted fact that the doctors

on the MCAP expressly agreed with Trigon (and the individual Trigon medical doctor employees on the MCAP) to issue the fraudulent treatment and lower back pain referral guideline that diverged from the well-supported federal guidelines and directly benefited medical doctors to the economic detriment of their competition, doctors of chiropractic, and their patients.

The Fourth Circuit Decision directly conflicts with holdings of the Sixth, Eighth and Eleventh Circuit Courts.

III. The Fourth Circuit Decision Has Overreaching And Dire Consequences For Antitrust Law

Since the inception of the Sherman Act, Congress and this Court have emphasized the heightened risk to competition from a combination of otherwise independent economic actors.

> The reason Congress treated concerted behavior more strictly than unilateral behavior is readily appreciated. Concerted activity inherently is fraught with anticompetitive risk. It deprives the marketplace of the independent centers of decisionmaking that competition assumes and demands. In any conspiracy, two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit. This not only reduces the diverse directions in which economic power is aimed but suddenly increases the economic power moving in one particular direction. Of course, such mergings of resources may well lead to efficiencies that benefit consumers, but their anticompetitive potential is sufficient to warrant scrutiny even in the absence of incipient monopoly.

Copperweld, 467 U.S. at 768-69, 104 S. Ct. at 2740; *see also Allied Tube*, 486 U.S. at 500, 108 S. Ct. at 1937 (standard-setting associations have serious potential for anticompetitive harm).

The Fourth Circuit has, in its Decision, directly and completely diverged from that clear jurisprudence. The Fourth Circuit provided no analysis, and cited no specific facts (contested or otherwise), to support its very conclusory result. The entire recitation by the Fourth Circuit is as follows.

> Applying this reasoning here, we agree with the district court that, under the intracorporate immunity doctrine, Trigon lacked the legal capacity to conspire with the medical doctors on the MCAP. American Chiropractic argues that because the medical doctors on the MCAP do not share a unity of interest with Trigon, the MCAP cannot be considered a corporate agent of Trigon. A similar argument was raised and rejected in *Oksanen*. There, the plaintiff had alleged that the medical doctors on the peer review committee did not have a unity of interest with the hospital because the medical doctors would act in their own best interest, not the best interest of the hospital. As mentioned above, we found that the medical doctors, in their role as members of the peer review committee, had a unity of interest with the hospital: ensuring patient care. We believe that *Oksanen's* reasoning is not only instructive but persuasive here.
>
> American Chiropractic is undoubtedly correct that medical doctors and insurance companies do not, generally speaking, share a unity of interest. That, however, is not the correct inquiry in cases applying the intracorporate immunity doctrine. Instead, we look to whether the medical doctors, in their role as members of the MCAP, share a unity of interest with Trigon that makes them corporate agents of Trigon. We believe that they do.
>
> Because Trigon established the MCAP to offer input on clinical issues faced by Trigon, the individual medical doctors, in their role as members

> of the MCAP, shared the same interest as Trigon: addressing clinical issues in a manner that would best serve its consumers, the plan enrollees. The MCAP is without question a corporate agent of Trigon, chaired by a Trigon employee, and we believe that the intracorporate immunity doctrine applies to its actions. The decision to consult with doctors on the MCAP does not "represent the sudden joining of economic forces that section one is designed to deter and penalize." *Oksanen, 945 F.2d at 703.* By creating the MCAP, Trigon did not bring together independent economic forces. Instead, Trigon had "ultimate control" over the MCAP's actions and was able to employ the MCAP to pursue its interests. In fact, we are presented with even stronger reasons for applying the doctrine here than we were in Oksanen because, in Oksanen, the peer review committee and the hospital were legally distinct entities. The MCAP is not legally distinct from Trigon.
>
> American Chiropractic's argument paints with too broad a brush, and would, in effect, undercut much of the rationale of the intracorporate immunity doctrine by focusing on form over substance. Penalizing "coordinated conduct simply because a corporation delegated certain responsibilities to autonomous units might well discourage corporations from creating divisions with their presumed benefits." *Copperweld, 467 U.S. at 771.* "Far from being a competitor with [Trigon], the [MCAP] was in fact a natural component of [Trigon's] management structure." *Oksanen, 945 F.2d at 703.*

App. 16a - 18a. This cursory opinion is faulty. The only thing in common between Trigon and the medical doctor representatives from Virginia's medical societies was the desire to prevent referrals to competitive chiropractors.

The Fourth Circuit Decision effectively revokes Section One of the Sherman Act. According to the Fourth Circuit, as soon as and simply because independent economic actors combine for a common purpose, they "share a unity of interest" and as such necessarily become "agents" of one another that cannot as a matter of law conspire or combine. That logic is perfectly circular -- and disastrous to antitrust jurisprudence.

It is apparent, and conceded in this case, that medical doctors and healthcare insurers are independent economic actors. *See* App. 17a. Thus, their combination, as the MCAP or in any other form, is inherently fraught with anticompetitive risk. *See, e.g. Allied Tube*, 486 U.S. at 505, 108 S. Ct. at 1937.

The Fourth Circuit did not carve out a limited exception to Section One, which would somehow apply to the otherwise inherently anticompetitive combination of the MCAP. Instead, it issued a blanket rule that, once otherwise independent actors join in a common plan, they become "one entity" which is thereby incapable of conspiring or combining. Although the Fourth Circuit cites one (Fourth Circuit) case to superficially apply the intracorporate immunity doctrine, that case (as well as that doctrine) is clearly not applicable here where non-corporate actors are admittedly separate and independent economic entities.

The medical doctors on the MCAP were appointed as representatives of the various Virginia medical associations. App. 1103a - 04a. The clear documentary evidence presented to the District Court and to the Fourth Circuit demonstrated this. *See supra*, p. 9. Trigon is Virginia's largest private insurance company. App. 79a, 130a. The agreement reached by members of the MCAP and Trigon directly affected the medical trade in Virginia -- benefiting medical doctors and harming chiropractic and its patients. Thus, the medical doctor associations and the insurance company did not have the unwavering unity of interest required in *Copperweld* for application of intracorporate immunity. *See Copperweld*, 467 U.S. at 771, 104 S. Ct. at 2741-

42. The combination of the medical doctor associations and the insurance company did, in fact, represent a "sudden joining of economic resources that had previously served different interests." *See Copperweld*, at 467 U.S. at 771, 104 S. Ct. at 2741-42. Moreover, the Virginia-wide back pain treatment standards established by the MCAP not only had a serious potential for anticompetitive harm (*see Allied Tube*, 486 U.S. at 505, 108 S. Ct. at 1937); the evidence was that they indeed harmed competition with chiropractors to the tune of tens of millions of dollars. App. 1105a-1153a.

The Fourth Circuit Decision stands antitrust jurisprudence on its head. If it is allowed to stand as precedent in the Fourth Circuit, the Decision will revoke Section One of the Sherman Act in that Judicial Circuit and further confuse the intra-corporate immunity doctrine throughout the United States.

IV. This Court Should Take This Opportunity To Clarify The Law Of "Single Entity Immunity"

Prior to *Copperweld*, the "intracorporate immunity doctrine" was less than clear. Lower courts and commentators alike struggled with its application to complex antitrust settings. *See Copperweld*, 467 U.S. at 767, 104 S. Ct. at 2740. In *Copperweld*, this Court took the opportunity to establish a clear rule of law regarding the inability of corporations and their subsidiaries to combine in violation of the Sherman Act, Section One.

Since *Copperweld*, however, the lower courts have struggled to determine when and whether non-corporate entities "combine" in violation of the Sherman Act Section One. *Compare Nurse Midwifery Ass'n*, 918 F.2d 605 (6th Cir. 1990); and *Mt. Pleasant*, 838 F.2d 268 (8th Cir. 1988); and *Bolt*, 891 F.2d 810 (11th Cir. 1990); with *Okusami v. Psychiatric Inst.*, 959 F.2d 1062, 1065 (D.C. Cir. 1992) (finding no basis for proposition that hospital and its medical staff have divergent interests); *Oksanen v. Page Mem'l Hosp.*, 945 F.2d 696, 705 (4th Cir. 1991) (en banc) (stating that hospital and its staff should not be seen as possible co-conspirators);

and *Nanavati v. Burdette Tomlin Mem'l Hosp.*, 857 F.2d 96, 118 (3d Cir. 1988) (concluding hospital could not conspire with executive committee); *see also* Craig W. Dallon, *Understanding Judicial Review of Hospitals' Physician Crendentialing And Peer Review Decisions*, 73 TEMPLE L. REV. 597, 659-60, and n. 424 (2000) (citing cases and noting conflicting holdings). App. 619a – 797a.

The First Circuit, in *Fraser v. Major League Soccer, LLC*, 284 F.3d 47 (1st Cir. 2002), expounded on the struggle by the Circuit Courts to apply the intra-corporate immunity doctrine to non-corporate entities. In *Fraser*, soccer player plaintiffs sued the newly-formed Major League Soccer sports league. The league and its teams were all owned by a parent Limited Liability Corporation, but with many complex private ownership interests throughout. Each team and its private owner expressly agreed with the parent corporation owner on all major aspects of team ownership, including player salaries, intellectual property, and many other details. 284 F.3d at 52-55. A central legal issue in the case was whether the various defendants (essentially, the individual teams and the parent league) should be treated as a single entity for purposes of Section One of the Sherman Act. *Id.*, at 55-56.

The First Circuit outlined the varying different outcomes of other Circuit Courts and expressed the difficulties of determining "single entity" status vis-à-vis Section One of the Sherman act.

> *Copperweld* established that a parent and its wholly owned subsidiary are not subject to attack under Section 1 for agreements between them. They are treated for Section 1 purposes as a single economic actor. But what the Supreme Court has never decided is how far *Copperweld* applies to more complex entities and arrangements that involve a high degree of corporate and economic integration but less than that existing in *Copperweld* itself.
>
> * * *

> To sum up, the present case is not *Copperweld* but presents a more doubtful situation; ... The law at this point could develop along either or both of two different lines.
>
> * * *
>
> Once one goes beyond the classic single enterprise, including *Copperweld* situations, it is difficult to find an easy stopping point or even decide [the "single entity" issue] on the proper functional criteria for hybrid cases.

Id., at 56, 58, 59 (underlining added).

The Fourth Circuit Decision at issue is a present-day manifestation of the lack of clarity or understanding within the individual Circuits of when, exactly, multiple non-corporate actors should or should not be deemed a "single entity" for antitrust purposes.

Medical doctor employees of Trigon, representing Trigon (Virginia's largest health insurance company), combined with medical doctors representing every major medical doctor association in Virginia, and published to over 90% of the medical doctors in Virginia false industry standards for treatment and insurance reimbursement guidelines for lower back pain. The false guidelines unlawfully excluded chiropractors and their proven superior services.

These actors had independent economic interests, and were not "corporate agents." Although there was, in fact, a stated common goal of the MCAP, the medical doctor trade association representative participants did not ever shed their underlying personal economic interests as healthcare providers. That would seem to necessitate heightened scrutiny for antitrust purposes. Surprisingly, however, the Fourth Circuit summarily concluded that, simply because the different actors formed a panel for a stated common goal, they necessarily as a matter of law could not "contract, combine or conspire" under Section One of the Sherman Act for any purpose. The law in the Circuits needs to be

defined. The Circuit Courts need guidance as to the meaning of "single entity immunity" under Section One of the Sherman Act.

CONCLUSION

As the Supreme Court has stated:

> Antitrust laws in general, and the Sherman Act in particular, are the Magna Carta of free enterprise. They are as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms.

United States v. Topco Assocs., Inc., 405 U.S. 596, 610, 92 S. Ct. 1126, 1135 (1972).

For all of the foregoing reasons, plaintiffs request that this Court grant this Petition for Writ of Certiorari.

Respectfully submitted,

George P. McAndrews
Counsel of Record
Steven J. Hampton
Patrick J. Arnold, Jr.
Sharon Hwang
James P. Murphy
Peter J. McAndrews
Ronald A. Dicerbo
McANDREWS, HELD & MALLOY, LTD.
500 West Madison Street, Suite 3400
Chicago, Illinois 60661
(312) 775-8000

Thomas R. Daly
ODIN, FELDMAN, AND PITTLEMAN, P.C.
9032 Lee Highway
Suite 1100
Fairfax, Virginia 22031

William G. Shields
THORSEN & SCHER
3810 Augusta Avenue
Richmond, Virginia 23230
(804) 359-3000

Counsel for Petitioners
AMERICAN CHIROPRACTIC
ASSOCIATION, AND VIRGINIA
CHIROPRACTIC ASSOCIATION, ET AL.

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In The
Supreme Court of the United States

AMERICAN CHIROPRACTIC ASSOCIATION, INCORPORATED, a non-profit corporation, *et al.*,
Petitioners,

v.

TRIGON HEALTHCARE, INCORPORATED, *et al.*,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

APPENDIX A (VOL. I OF III) TO
PETITION FOR WRIT OF CERTIORARI

George P. McAndrews
Counsel of Record
Steven J. Hampton
Patrick J. Arnold, Jr.
Sharon Hwang
James P. Murphy
Peter J. McAndrews
Ronald A. Dicerbo
MCANDREWS, HELD & MALLOY, LTD.
34th Floor
500 West Madison Street
Chicago, IL 60661
(312) 775-8000

Thomas R. Daly
ODIN, FELDMAN, & PITTLEMAN, P.C.
9032 Lee Highway
Suite 1100
Fairfax, VA 22031
(703) 218-2100

William G. Shields
THORSEN & SCHER
3810 Augusta Ave.
Richmond, VA 23230
(804) 359-3000

Counsel for Petitioners

THE LEX GROUP ♦ 1108 East Main Street ♦ Suite 1400 ♦ Richmond, Virginia 23219
(804) 644-4419 ♦ (800) 856-4419 ♦ Fax: (804) 644-3660 ♦ www.thelexgroup.com

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Re: *WILK, D.C., et al. v.*
AMERICAN MEDICAL ASSOCIATION, et al.
dated February 7, 1990 ..... 393a

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PUBLISHED
UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

03-1675

AMERICAN CHIROPRACTIC ASSOCIATION, INCORPORATED, a nonprofit corporation; VIRGINIA CHIROPRACTIC ASSOCIATION, INCORPORATED; GEORGE W. CHIRIKINIAN, D.C.; DOUGLAS M. COX, D.C.; WILLIAM R. THEISIER, D.C.; JOHN C. WILLIS, D.C.; JERRY R. WILLIS, D.C.; SARAH ELIZABETH ALLEN; LANA KAY BALL; MARGARET BYRNE; ROGER DALTON; MARY SUE DEAN; HARVIE LEE FRENCH, JR.; PATRICIA HERMAN; CINDY LINKENHOKER; SANDRA PHILLIPPI; DARLENE REQUIZO; DAVID RUSSOTTO; GLORIA JEAN SMITH; LYNN D. WAGNER; ANDREA WALLACE; PATRICIA WHITTINGTON; BENIS D. WOOD; RICHARD D. WORLEY; DALE DUKE YONTZ; DOUGLAS F. AMBROSE; GEORGE C. MCCLELLAND; JAMES M. PORTER; LARRY L. STINE; WENDY HOLDEN WILLIS; STEVEN W. YATES; KEVIN J. WESTBY; GREGORY WALTER; JEFFERSON K. TEASS,

Plaintiffs-Appellants,

v.

TRIGON HEALTHCARE, INCORPORATED; TRIGON INSURANCE COMPANY; TRIGON ADMINISTRATORS; MID-SOUTH INSURANCE COMPANY; TRIGON HEALTH AND LIFE INSURANCE COMPANY,

Defendants-Appellees,

and

BLUE CROSS AND BLUE SHIELD ASSOCIATION,

Defendant.

Appeal from the United States District Court for the Western District of Virginia, at Abingdon.
James P. Jones, District Judge.
(CA-00-113-1)

Argued: February 24, 2004

Decided: May 6, 2004

[ENTERED: MAY 6, 2004]

Before WILLIAMS and MICHAEL, Circuit Judges, and William D. QUARLES, Jr., United States District Judge for the District of Maryland, sitting by designation.

Affirmed by published opinion. Judge Williams wrote the opinion, in which Judge Michael and Judge Quarles joined.

COUNSEL

ARGUED: George P. McAndrews, MCANDREWS, HELD & MALLOY, LTD., Chicago, Illinois, for Appellants. Howard Feller, Bryan Alan Fratkin, MCGUIREWOODS, L.L.P., Richmond, Virginia, for Appellees. **ON BRIEF:** Steven J. Hampton, Patrick J. Arnold, Jr., Peter J. McAndrews, Ronald A. Dicerbo, MCANDREWS, HELD & MALLOY, LTD., Chicago, Illinois; William G. Shields, THORSEN & SCHER, Richmond, Virginia, for Appellants.

OPINION

WILLIAMS, Circuit Judge:

In this appeal, we consider whether Trigon Healthcare, Virginia's largest for-profit health insurance company, and its affiliated companies (collectively, Trigon),[1] were engaged in an anticompetitive conspiracy with medical doctors and medical associations whose purpose was to harm chiropractors. American Chiropractic[2] filed this eight count complaint alleging violations of federal antitrust laws, the Racketeer Influenced and Corrupt Organizations Act (RICO), and various state laws, claiming that Trigon and the medical doctors and associations were engaged in a conspiracy that used Trigon's reimbursement policies and treatment guidelines to limit severely the flow of insurance dollars to chiropractors and steer those monies toward medical doctors. Trigon argues that no conspiracy exists, and that it implemented its coverage policies unilaterally based on market supply and demand. The district court agreed with Trigon, dismissing two counts of the complaint for failure to state a claim and disposing of the remaining counts by granting Trigon's motion for summary judgment. Although we apply different reasoning than the district court in
some areas, we affirm its disposition of the case in favor of Trigon.

I.

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[1] Trigon Healthcare was recently purchased by Anthem Healthcare, an Indiana based health insurance company. To be consistent with the district court's usage and the factual record developed below, we refer to the corporation as "Trigon."

[2] We refer to the appellants, the American Chiropractic Association, the Virginia Chiropractic Association, certain individual chiropractors and some patients of individual chiropractors, collectively as "American Chiropractic."

Trigon is a for-profit, publicly-traded health insurance company located in Virginia. Trigon's business consists of selling individual and group healthcare benefit plans to its subscribers. Generally, these healthcare benefit plans list the benefits and services covered by Trigon under the plan and describe any services that are excluded from the plan or are the subject of coverage limitations. Trigon makes a network of healthcare providers, including medical doctors, hospitals, pharmacies, chiropractors, and therapists, available to plan members to provide the services covered under the plan. Trigon creates this network of healthcare providers by entering into contracts with providers who are willing to abide by Trigon's terms and conditions, as set forth in Trigon's provider agreements. Simply put, "Trigon is essentially purchasing services from the healthcare providers who agree to become participating providers in Trigon's [provider] networks." (J.A. at 1344.) Trigon strives to offer "the best coverage at the lowest possible cost," and it endeavors to pay "the lowest possible price" to healthcare providers to ensure low-cost access for plan enrollees. (J.A. at 1597, 4579.)

Chiropractic medicine is "a non-pharmaceutical, nonsurgical system of health care based on the self-healing capacity of the body" with the aim of "removing irritants to the nervous system and restoring proper function" to the nervous system. *Dorland's Medical Illustrated Dictionary* 347 (30th ed. 2003). Chiropractic treatment most commonly involves spinal manipulations[3] to relieve musculoskeletal complaints. *Id.* Trigon has provided coverage for chiropractic services since the 1980's, and Trigon

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[3] Spinal manipulation is defined by the Agency for Health Care Policy and Research, a division of the U.S. Department of Health and Human Services, as "manual therapy in which loads are applied to the spine using short or long lever methods." (J.A. at 5507.)

"acknowledge[s] that chiropractic care has a health effect, a positive health effect when rendered appropriately." [4] (J.A. at 4186.)

Despite Trigon's coverage of chiropractic services, and the fact that chiropractic medicine is, as the district court noted, a "recognized branch of the healing arts," *see American Chiropractic Association v. Trigon Healthcare, Inc.*, 258 F. Supp. 2d 461, 463 (W.D. Va. 2003), there is a history of animus from medical doctors and insurers aimed at chiropractors. Beginning in 1962, the American Medical Association (AMA), aided by the National Association of Blue Shield Plans,[5] began a "lengthy, systematic, successful, and unlawful" national group boycott aimed at destroying chiropractic medicine. *Wilk v. Am. Medical Ass'n.*, 895 F.2d 352, 371 (7th Cir. 1990). As the Seventh Circuit explained:

> In 1963 the AMA formed its Committee on Quackery ("Committee"). The Committee worked diligently to eliminate chiropractic. A primary method to achieve this goal was to make it unethical for medical physicians to professionally associate with chiropractors. Under former Principle 3, it was unethical for

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[4] The use of chiropractors by Trigon's plan enrollees has increased substantially since Trigon began covering chiropractic care. For instance, in 1996 only 26,275 plan enrollees received spinal manipulation treatment from chiropractors, but that number jumped to 74,477 by 2001. The number of chiropractic providers in Trigon's network rose from 513 to 961 during the same time span, and now almost 90% of chiropractors in the Commonwealth of Virginia are in Trigon's provider network. In addition, the total amount of payments from Trigon to chiropractors rose from $12,380,737 in 1996 to $21,510,503 in 2001.

[5] This organization is now called Blue Cross & Blue Shield Association of America.

> medical physicians to associate with "unscientific practitioners." In 1966, the AMA's House of Delegates passed a resolution labelling chiropractic an unscientific cult.

Id. at 356.

Beginning in 1977, the AMA slowly began to phase out its boycott of chiropractors, and the Seventh Circuit adopted the *Wilk* district court's finding that the boycott became dormant in 1980 when Principle 3 was revised.[6] *Id.* at 356, 374. Although Trigon is a licensee of Blue Cross & Blue Shield Association of America, there is no record evidence connecting Trigon to this boycott.

American Chiropractic, however, asserts that medical doctors continue
to harbor animosity toward chiropractors and have entered into an anticompetitive conspiracy with Trigon to harm chiropractors. American Chiropractic contends that medical doctors and their medical associations have conspired with Trigon to limit the usage of chiropractors by Trigon's plan enrollees and to restrain severely the reimbursement paid to chiropractors for services rendered to plan enrollees. The ultimate goal of this conspiracy, American Chiropractic argues, is to shift insurance dollars away from chiropractors toward medical doctors and harm the business of chiropractors.

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[6] Although the Seventh Circuit recognized that the boycott ended in 1980, it affirmed a grant of injunctive relief against the American Medical Association because some of its actions in 1983 "indicated the AMA's likelihood of returning to its old (anti-chiropractic) ways." *Wilk v. Am. Medical Ass'n.*, 895 F.2d 352, 367 (7th Cir. 1990).

In response to this perceived anticompetitive conspiracy, American Chiropractic brought this action in the United States District Court for the Western District of Virginia on August 18, 2000. American Chiropractic's eight-count complaint alleged that Trigon[7] conspired with medical doctors and medical associations to restrain interstate trade in violation of § 1 of the Sherman Antitrust Act, 15 U.S.C.A. § 1 (West 1997) (count one); attempted to monopolize the market for treatment of neuromusculoskeletal conditions in violation of § 2 of the Sherman Act, 15 U.S.C.A. § 2 (West 1997) (count two); engaged in a pattern of racketeering activity in violation of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C.A. § 1962 (West 2000) (count three); tortiously interfered with the business enterprise of chiropractors in violations of state common law (count four); conspired to injure chiropractors in their trade or practice in violation of Va. Code Ann. § 18.2-499 (Michie 1996) (count five); committed state common law breach of contract (count six) and conspiracy (count seven); and violated Va. Code Ann. §§ 38.2-2203, 38.2-3408, 38.2-4221, and 38.2-4312(E) (Michie 2002), referred to as the Virginia insurance equality laws (count eight). The district court exercised supplemental jurisdiction over the state law claims pursuant to 28 U.S.C.A. § 1367 (West 1993).

Trigon moved to dismiss the complaint in its entirety on October 13, 2000. The district court, on July 19, 2001, granted that motion in part and dismissed American Chiropractic's RICO (count three) and Virginia insurance equality (count eight) claims for failure to state claims. The district court held that the RICO claim was preempted by

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[7] The complaint initially named Blue Cross & Blue Shield of America in addition to Trigon Healthcare, Inc. and its affiliated companies. Blue Cross & Blue Shield of America was voluntarily dismissed as a defendant by American Chiropractic.

the McCarran-Ferguson Act and that the Virginia insurance equality laws relied upon by American Chiropractic did not create private causes of action.

Following discovery, on August 13, 2002, Trigon filed a motion for summary judgment on the remaining counts in the complaint. American Chiropractic did not file a Rule 56(f) motion requesting further discovery, but it did contest Trigon's motion for summary judgment. After the benefit of oral argument, the district court, on April 25, 2003, granted Trigon's motion for summary judgment on the remaining counts. As to counts one, five, and seven, the district court found that the intracorporate immunity doctrine precluded any conspiracy between Trigon and the medical doctors that served on one of its committees, the Managed Care Advisory Panel, and that American Chiropractic had produced no other evidence of a conspiracy between Trigon and the medical doctors or medical associations. As to American Chiropractic's claim for monopolization (count two), the district court granted summary judgment because Trigon did not possess monopoly power in the relevant market. It also granted Trigon's motion for summary judgment as to American Chiropractic's state law claims for tortious interference (count four) and breach of contract (count six). American Chiropractic noted a timely appeal of the district court's rulings, and we have jurisdiction under 28 U.S.C.A. § 1291.

On appeal, American Chiropractic argues: (1) that the district court erred in holding the intracorporate immunity doctrine applies to this case; (2) that the district court erred in holding that there was insufficient evidence of a conspiracy between Trigon and the medical associations to withstand summary judgment; (3) that the district court erred in granting summary judgment on the tortious interference claim; (4) that the district court erred in dismissing the Virginia insurance equality claim; (5) that the

district court erred in dismissing the RICO claim as preempted by the McCarran-Ferguson Act; and (6) that the district court abused its discretion in conducting discovery.[8] We address each contention in turn.

II.

Counts One, Five, and Seven

(The Conspiracy Counts)

American Chiropractic first contends that the district court erred in finding that the intracorporate immunity doctrine barred the possibility of a conspiracy between Trigon and its Managed Care Advisory Panel (MCAP) and in granting summary judgment on American Chiropractic's claim under §1 of the Sherman Act and its state law conspiracy claims.[9] We review the grant of summary judgment de novo, viewing the facts in the light most favorable to the non-moving party. *See Figgie Int'l, Inc. v. Destileria Serralles, Inc.*, 190 F.3d 252, 255 (4th Cir. 1999). Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving

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[8] We note that American Chiropractic does not appeal the district court's grant of summary judgment on its § 2 Sherman Act claim (count two) or the state law breach of contract claim (count six).

[9] Because the state law conspiracy claims follow the same analysis as the § 1 claim, we do not address them separately. *See Va. Vermiculite, Ltd. v. Historic Green Springs, Inc.*, 307 F.3d 277, 284 (4th Cir. 2002) (noting that the Virginia Civil Conspiracy Act does not create liability absent a violation of the federal antitrust laws); *Fox v. Deese*, 362 S.E.2d 699, 708 (Va. 1987) (adopting intracorporate immunity doctrine for Virginia conspiracy laws).

party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

Under its Section 1 claim, American Chiropractic alleged that Trigon and its MCAP, a committee established by Trigon, created false referral guidelines meant to limit the usage of chiropractors for the treatment of lower back pain and, accordingly, to keep insurance reimbursement monies away from chiropractors. Trigon established the MCAP, composed of six Trigon employees and nine independent medical doctors appointed by professional organizations,[10] to "obtain input and advice from medical doctors on clinical issues such as quality control initiatives." (J.A. at 1348.) The MCAP "was formed and appointed by officers and employees of Trigon." (J.A. at 1352.) Dr. Lawrence Colley, Trigon's Vice President for Corporate Medical Policy during the relevant time period, also served as a member of the MCAP. It is undisputed that the MCAP was never given information regarding specific payment policies and that it lacked any decisionmaking authority.

American Chiropractic points to the MCAP's approval, in October 1995, of Trigon's practice guideline, titled "Managing Low Back Problems in Adults" (the Low Back Guideline), as evidence of an anticompetitive conspiracy between the members of the MCAP and Trigon. (J.A. at 6119.) This Low Back Guideline was drafted as an informative practice guideline for physicians. The Guideline also did not bear any relation to Trigon's coverage and reimbursement policies.

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[10] These organizations include the Virginia Society of Internal Medicine, the Medical Society of Virginia, the American College of Physicians, the University of Virginia School of Medicine, the Eastern Virginia Medical School and other medical organizations.

(J.A. at 1539-40.) The Low Back Guideline was written by Trigon's employees, not the MCAP, and was issued in response to a lengthy study by the Agency for Health Care Policy and Research (AHCPR), a division of the U.S. Department of Health and Human Services.

The AHCPR study was titled "Acute Low Back Problems in Adults" and was accompanied by a reference guide for treating low back pain. The study recommended spinal manipulation "in place of medication or a shorter trial [of manipulation] if combined with NSAIDS"[11] for the treatment of low back pain. (J.A. at 5653.) The AHCPR study defined "manipulation" as "manual therapy in which loads are applied to the spine using short or long lever methods." (J.A. at 5507.) This definition of manipulation referred to the procedure rendered primarily by chiropractors, as opposed to medical doctors. One medical journal, the *Annals of Internal Medicine*, stated in July 1998 that "the [AHCPR] recently made history when it concluded that spinal manipulative treatment is the most effective and cost-effective treatment for acute low back pain." (J.A. at 4984.) American Chiropractic argues that this AHCPR study "was a boon to chiropractors and a setback for medical doctors." (Appellant's Br. at 22.)

Trigon intended its under ten page Low Back Guideline to be "a shortened and user-friendly format" of the over one-hundred and fifty page AHCPR study for health care providers. (J.A. at 1538.) The Low Back Guideline stated that it was "adapted from the [AHCPR] and . . . approved and endorsed by Trigon's Managed Care Advisory Panel." (J.A. at 6123.) The MCAP considered the Low Back Guideline, alongside two other practice guidelines, on October 25, 1995. During that meeting, one of

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[11] NSAIDs is an abbreviation for non-steroidal anti-inflammatory drugs such as aspirin and ibuprofen.

the medical doctors on the MCAP asked if the guidelines the MCAP was considering were meant to be referral guidelines. Dr. Colley told them that the guidelines were referral guidelines.[12] The MCAP then adopted and approved the Low Back Guideline without making or suggesting any changes to it.

American Chiropractic argues that the Low Back Guidelines are false and misleading in two principal ways. First, the Low Back Guideline provided that "[a] short trial of manipulation may be as effective as NSAIDs." (J.A. at 6120.) American Chiropractic contends that the AHCPR guideline stands for the proposition that manipulation is *more effective* than NSAIDs. Second, the Low Back Guideline did not define the term "manipulation." According to American Chiropractic, the absence of this definition meant that the Low Back Guideline deterred primary care physicians from referring patients to chiropractors because it failed to identify manipulation practiced by chiropractors as the specific type of manipulation recommended. Dr. Scott Haldeman, one of American Chiropractic's experts and a member of the AHCPR panel, opined that "[b]y omitting the AHCPR's definition of manipulation, Trigon and its Managed Care Advisory Panel materially altered the recommendations of the AHCPR." (J.A. at 5672.) Because of this omission, according to Dr. Haldeman, Trigon's guidelines would "deprive patients of the benefit from spinal manipulation as practiced by doctors of chiropractic, and . . . deprive doctors of chiropractic of the opportunity to treat those patients." (J.A. at 5672.)

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[12] It is unclear whether Dr. Colley was stating that the Low Back Guideline was a referral guideline, or if he was referencing one of the other guidelines before the Managed Care Advisory Panel. Because this fact does not affect our analysis on American Chiropractic's Section 1 claim, we will assume that Dr. Colley was referencing the Low Back Guideline.

The district court was not persuaded by American Chiropractic's argument, and held that, under the intracorporate immunity doctrine, Trigon was legally incapable of conspiring with the MCAP. Additionally, the district court then found that American Chiropractic had failed to adduce sufficient evidence of a conspiracy between Trigon and the medical associations who appointed individuals to the MCAP to survive summary judgment. On appeal, American Chiropractic argues that the intracorporate immunity doctrine does not apply, either because the medical doctors on the MCAP lacked a unity of interest with Trigon or because the independent personal stake exception to the doctrine should apply. American Chiropractic also contends that it has produced direct evidence of a conspiracy among Trigon and the medical doctors on the MCAP and the medical associations that appointed those doctors.

A.

We consider first American Chiropractic's argument that Trigon conspired with the medical doctors who served on the MCAP.[13] Section 1 of the Sherman Act provides, in relevant part, that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." 15 U.S.C.A. § 1. Thus, to establish a § 1 violation, a plaintiff must show: "(1) a contract, combination or conspiracy; (2) that imposed an unreasonable restraint of trade." *Dickson v. Microsoft Corp.*, 309 F.3d 193, 202 (4th Cir. 2002). "It is incontestable that 'concerted action' in restraint of trade lies at the heart of a Sherman Act section 1 violation." *Va. Vermiculite, Ltd. v. Historic Green Springs, Inc.*, 307 F.3d 277, 280 (4th Cir. 2002).

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[13] American Chiropractic did not argue that Trigon conspired with its own employees serving on the MCAP.

In other words, § 1 "does not reach conduct that is wholly unilateral." *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984) (internal quotation marks omitted).

"Proof of concerted action requires evidence of a relationship between at least two legally distinct persons or entities." *Oksanen v. Page Memorial Hosp.*, 945 F.2d 696, 702 (4th Cir. 1991) (en banc). Thus,

> it is perfectly plain that an internal 'agreement' to implement a single, unitary firm's policies does not raise the antitrust dangers that § 1 was designed to police. The officers of a single firm are not separate economic actors pursuing separate economic interests, so agreements among them do not suddenly bring together economic power that was previously pursuing divergent goals.

Copperweld, 467 U.S. at 769. Moreover, "§ 1 is not violated by the internally coordinated conduct of a corporation and one of its unincorporated divisions." *Id.* at 770. "For similar reasons, the coordinated activity of a parent and its wholly owned subsidiary must be viewed as that of a single enterprise for purposes of § 1 of the Sherman Act." *Id.* at 771. Accordingly, the Supreme Court has held that a parent and its wholly owned subsidiary are legally "incapable of conspiring with each other for purposes of § 1 of the Sherman Act." *Id.* at 777. The Court in *Copperweld* noted further that "a parent and a wholly owned subsidiary *always* have a 'unity of purpose or a common design'" so the law's concern with a sudden joining of independent interests is not present in such a case. *Id.* at 771 (emphasis added).

We have applied this "intracorporate immunity" doctrine articulated in *Copperweld* to hold that a hospital lacked the capacity to conspire with its peer review

committee for purposes of § 1. *See Oksanen*, 945 F.2d at 706.[14] The plaintiff in *Oksanen*, a doctor, contended that the hospital conspired with its peer review committee, composed of staff physicians at the hospital, to limit and then revoke his staff privileges. Although the hospital and its medical staff were "legally separate entities," we held that the intracorporate immunity doctrine applied, explaining that "we must examine the substance, rather than the form, of the relationship between the hospital and the medical staff during the peer review process." *Id.* at 703. We concluded that the hospital and the doctors on the peer review committee possessed a unity of interest: improving the quality of patient care. "Like a corporation delegating authority to its officers, the [hospital] delegated peer review decisionmaking in the first instance to the medical staff." *Id.* at 703. Thus, "[i]n effect, the medical staff was working as the [hospital's] agent." *Id.*; *see also Detrick v. Panalpina, Inc.*,108 F.3d 529, 544 (4th Cir. 1997) ("The intracorporate immunity doctrine provides that a conspiracy can not exist between the agents of a corporation and the corporation itself."); *ePlus Technology v. Aboud*, 313 F.3d 166, 179 (4th Cir. 2002) ("[A]cts of corporate agents are acts of the corporation itself, and corporate employees cannot conspire with each other or with the corporation."). Moreover, the hospital "retained ultimate responsibility for all of the hospital's credentialing decisions." *Oksanen*, 945 F.2d at 704. The hospital's "ultimate control over peer review decisions enable[d] it to employ peer review to pursue its interests." *Id.* Finally, we questioned whether hospitals possessed any economic motive for conspiring with some medical doctors

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[14] A lawsuit alleging a conspiracy between a hospital and its peer review committee currently would be barred under the Health Care Quality Improvement Act of 1986. 42 U.S.C.A. §§ 11101-11152 (West 1995 & Supp. 2003). That Act was passed after the filing of Oksanen's lawsuit and was not made retroactive to pending cases.

to exclude others from the staff: "[i]f a physician is qualified and does not disrupt the hospital's operations, it is in the hospital's interest to include, not exclude, that physician." *Id.*; *see also* P. Areeda and H. Hovenkamp, *Antitrust Law* ¶ 1471b (1999 Supp.).

We have continued to recognize the existence of one narrow exception to the intracorporate immunity doctrine — the independent personal stake exception. In *Greenville Pub. Co. v. Daily Reflector, Inc.*, 496 F.2d 391 (4th Cir. 1974), we held that an exception to the intracorporate immunity doctrine "may be justified when the officer has an independent personal stake in achieving the corporation's illegal objective." *Id.* at 399. We declined an invitation to apply the exception in *Oksanen* because the peer review committee lacked the ability to bind the hospital. "If the officer cannot cause a restraint to be imposed and his firm would have taken the action anyway, then any independent interest is largely irrelevant to antitrust analysis." *Oksanen*, 945 F.2d at 705. Put differently, "[t]o give advice when asked by the decisionmaker is not equivalent to being the decisionmaker itself." *Pennsylvania Dental Ass'n. v. Medical Serv. Ass'n.*, 745 F.2d 248, 259 (3d Cir. 1984).

Applying this reasoning here, we agree with the district court that, under the intracorporate immunity doctrine, Trigon lacked the legal capacity to conspire with the medical doctors on the MCAP. American Chiropractic argues that because the medical doctors on the MCAP do not share a unity of interest with Trigon, the MCAP cannot be considered a corporate agent of Trigon. A similar argument was raised and rejected in *Oksanen*. There, the plaintiff had alleged that the medical doctors on the peer review committee did not have a unity of interest with the hospital because the medical doctors would act in their own best interest, not the best interest of the hospital. As mentioned above, we found that the medical doctors, in

their role as members of the peer review committee, had a unity of interest with the hospital: ensuring patient care. We believe that *Oksanen*'s reasoning is not only instructive but persuasive here.

American Chiropractic is undoubtedly correct that medical doctors and insurance companies do not, generally speaking, share a unity of interest. That, however, is not the correct inquiry in cases applying the intracorporate immunity doctrine. Instead, we look to whether the medical doctors, in their role as embers of the MCAP, share a unity of interest with Trigon that makes them corporate agents of Trigon. We believe that they do.

Because Trigon established the MCAP to offer input on clinical issues faced by Trigon, the individual medical doctors, in their role as members of the MCAP, shared the same interest as Trigon: addressing clinical issues in a manner that would best serve its consumers, the plan enrollees. The MCAP is without question a corporate agent of Trigon, chaired by a Trigon employee, and we believe that the intracorporate immunity doctrine applies to its actions. The decision to consult with doctors on the MCAP does not "represent the sudden joining of economic forces that section one is designed to deter and penalize." *Oksanen*, 945 F.2d at 703. By creating the MCAP, Trigon did not bring together independent economic forces. Instead, Trigon had "ultimate control" over the MCAP's actions and was able to employ the MCAP to pursue its interests. In fact, we are presented with even stronger reasons for applying the doctrine here than we were in *Oksanen* because, in *Oksanen*, the peer review committee and the hospital were legally distinct entities. The MCAP is not legally distinct from Trigon.

American Chiropractic's argument paints with too broad a brush, and would, in effect, undercut much of the rationale of the intracorporate immunity doctrine by focusing on form over substance. Penalizing "coordinated conduct simply because a corporation delegated certain responsibilities to autonomous units might well discourage corporations from creating divisions with their presumed benefits." *Copperweld*, 467 U.S. at 771. "Far from being a competitor with [Trigon], the [MCAP] was in fact a natural component of [Trigon's] management structure. " *Oksanen*, 945 F.2d at 703.

Moreover, the independent personal stake exception does not apply because the MCAP did not have the power to bind Trigon; it only made non-binding recommendations and endorsed materials already composed by Trigon employees. In fact, the MCAP did not even recommend changes to the Low Back Guideline. While the MCAP's seal of approval was important to Trigon from a business perspective because it allowed Trigon to market various publications as approved by a panel of medical doctors, American Chiropractic has made no showing that the MCAP itself could rewrite any part of such a publication and make Trigon issue those rewritten publications. The ultimate decision as to the contents of any document before the MCAP always rested with Trigon, and, accordingly, the independent personal stake exception cannot apply. *See id.* at 705.

Thus, we agree with the district court that Trigon lacked the capacity to conspire, within the meaning of § 1, with its corporate agent, the MCAP or its members.

B.

American Chiropractic next argues, assuming that the MCAP did not conspire with Trigon, that the medical associations who placed their members on the MCAP conspired with Trigon to publish the allegedly misleading guidelines and to implement several coverage policies aimed at limiting the usage and reimbursement of chiropractic services. As discussed above, to establish a § 1 violation, a plaintiff must show: "(1) a contract, combination, or conspiracy, (2) that imposed an unreasonable restraint of trade." *Dickson*, 309 F.3d at 202. A plaintiff can offer direct or circumstantial evidence to prove concerted action. *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 774 (1984). American Chiropractic argues on appeal that it provided direct evidence of this conspiracy, in the form of the minutes from the MCAP meeting where the MCAP approved the Low Back Guideline, and the Low Back Guideline itself. These minutes and the Low Back Guideline, American Chiropractic alleges, represent direct evidence of a conspiracy orchestrated between the medical associations and Trigon. Additionally, American Chiropractic argues that it presented direct evidence that Trigon and the medical associations conspired to implement two other coverage policies with the intent to harm chiropractors – a $500 cap on spinal manipulations and a reduced reimbursement rate for chiropractors and other limited license providers.

In 1988, Trigon instituted a $500 yearly reimbursement cap on spinal manipulations, regardless of "what type of provider renders the services." (J.A. at 5345.) Although this $500 reimbursement cap is facially neutral, in that it does not target a specific provider, neither side disputes that chiropractors are the main providers of spinal manipulations. One chiropractor testified that no other insurance company had a cap as harsh as Trigon's, and that a "majority" of insurance companies did not use a hard

coverage cap on spinal manipulations. (J.A. at 7900, 7903-04.) This $500 annual coverage limit on spinal manipulations has remained in place since 1988.

In 1996, Trigon lowered the reimbursement rate for limited-license practitioners,[15] including chiropractors, to 60% (from 70%) of that received by fully-licensed practitioners performing the same procedure. As explained by Trigon, "the marketplace for third party healthcare coverage is extremely competitive and our customers are extremely price sensitive," making the lower reimbursement rate "appropriate and reasonable." (J.A. at 4636, 6337.)

American Chiropractic argues that both of these policies resulted from a conspiracy between Trigon and the medical associations. The $500 annual cap, American Chiropractic asserts, was implemented with the purpose of limiting the utilization of chiropractic services, while the lower reimbursement rate was intended to shift insurance dollars from chiropractors to medical doctors. American Chiropractic argues that, because Trigon recognizes that chiropractic care is effective and inexpensive, policies like these that have an adverse effect on chiropractic care are direct evidence that Trigon is not making an independent economic judgment but rather conspiring to harm chiropractors.

"[A]ntitrust law limits the range of permissible inferences from ambiguous evidence in a § 1 case." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986). Direct evidence is extremely rare in antitrust cases and is usually referred to as the "smoking gun." *InterVest, Inc. v. Bloomberg, L.P.*, 340 F.3d 144, 159 (3d Cir.

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[15] Limited-license providers are defined by Trigon to include chiropractors, speech therapists, occupational therapists and physical therapists.

2003). We agree with the Third Circuit that direct evidence in this context is "explicit and requires no inferences to establish the proposition or conclusion being asserted." *Id.* (quotation marks omitted); *see United Mine Workers of Am. v. Pennington*, 381 U.S. 676, 720 (1965) (Goldberg, J., dissenting) ("Only rarely will there be direct evidence of an express agreement" in conspiracy cases). American Chiropractic's offering falls far short of this standard. At most, the MCAP meeting shows contact between two independent economic actors, but "mere contacts and communications, or the mere opportunity to conspire, among antitrust defendants is insufficient evidence [of] an anticompetitive conspiracy." *Cooper v. Forsyth County Hosp. Auth.*, 789 F.2d 278, 281 (4th Cir. 1986). The two coverage policies are also not direct evidence of a conspiracy because both require the rather large inferential leap that Trigon drafted and implemented the policies only after reaching an agreement with medical doctors and associations.

Furthermore, as the district court explained,[16] American Chiropractic has not entered sufficient indirect evidence of a conspiracy to harm chiropractors. It is undisputed that use of chiropractic treatment by Trigon subscribers has substantially increased since the Low Back Guideline was issued in 1996. *See supra* note 4. Since 1996, the amount of money paid to chiropractors by Trigon has also risen substantially, from approximately $12 million dollars to over $21 million in 2001. The reimbursement policies about which American Chiropractic complains are facially neutral policies that admittedly have an effect on chiropractors. There is, however, no evidence of an effort by

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[16] American Chiropractic also limited its arguments to direct evidence of a conspiracy before the district court, but that court found that American Chiropractic offered no direct evidence of a conspiracy and instead analyzed whether there was circumstantial evidence of a conspiracy.

Trigon to harm chiropractors apart from these facially neutral reimbursement policies and the Low Back Guideline, and, more importantly, American Chiropractic has failed to show that either the reimbursement policies or the Low Back Guideline was the result of an antitrust *conspiracy*. They have pointed to no evidence that Trigon conspired with any entity in forming its policies. In fact, the only evidence in the record is that all of the actions in dispute were taken unilaterally by Trigon employees. In the face of Trigon's affidavits that it acted unilaterally, American Chiropractic needed more to create a genuine issue of material fact.

Moreover, American Chiropractic has not explained why Trigon would, as an economic matter, attempt to exclude chiropractors from its provider network or dissuade patients from the use of chiropractic services if chiropractic care is more cost-effective than other medical care. As the district court ably explained, *see Trigon Healthcare*, 258 F. Supp. 2d at 466-67, this alleged conspiracy does not make economic sense from Trigon's perspective. We agree with the district court that, "as a profit-seeking corporation, [Trigon] had no economic motive to prevent referrals to chiropractors." *Id.* at 466.

Accordingly, we affirm the district court's grant of summary judgment on American Chiropractic's claim under § 1 of the Sherman Act (count one) and its state law conspiracy claims (counts five and seven).[17]

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[17] Because we find that American Chiropractic failed to prove the existence of an anticompetitive conspiracy, we do not consider whether American Chiropractic entered sufficient evidence that Trigon and the medical associations and medical doctors implemented unreasonable restraints on trade.

III.

Count Four

(Tortious Interference)

American Chiropractic next challenges the grant of summary judgment in favor of Trigon on its state law claim for tortious interference. We review the grant of summary judgment de novo. *Figgie Int'l*, 190 F.3d at 255. Virginia law permits recovery for such claims where a party can show "(1) the existence of a business relationship or expectancy, with a probability of future economic benefit to plaintiff; (2) the defendant's knowledge of the relationship or expectancy; (3) a reasonable certainty that absent defendant's intentional misconduct, plaintiff would have continued in the relationship or realized the expectancy; and (4) damages to plaintiff." *Commercial Bus. Sys., Inc. v. Halifax Corp.*, 484 S.E.2d 892, 896 (Va. 1997) (quotation marks omitted). "[P]roof of the existence of the first and third elements of the tort must meet an objective test," and "mere proof of a plaintiff's belief and hope that a business relationship will continue is inadequate to sustain the cause of action." *Id.* at 897. Instead, a plaintiff must "establish a *probability* of future economic benefit, not a mere possibility." *Id.* (emphasis added). When a plaintiff is alleging that a third party has interfered with a business expectancy rather than with an actual contract, the plaintiff must "show that the defendant interfered by employing improper methods." *Peterson v. Cooley*, 142 F.3d 181, 186 (4th Cir. 1998). Improper methods are "those means that are illegal or independently tortious, such as violations of statutes, regulations, or recognized common-law rules." *Duggin v. Adams*, 360 S.E.2d 832, 836 (Va. 1987).

Under this count, American Chiropractic argues that the $500 annual coverage cap on spinal manipulations tortiously interfered with the chiropractors' business expectancy that their patients would continue to seek treatment from them. This argument fails because American Chiropractic has not shown a business expectancy with a probability of future economic benefit. Virginia law requires objective proof of a probability of future economic benefit, not just a hope or a belief that a business relationship will continue. American Chiropractic admitted that patients have the ability and the right to terminate their relationship at any time, and it has not introduced any evidence showing more than a hope or belief that, generally speaking, patients would continue seeking treatment from chiropractors. The chiropractors never had written contracts with their patients, and some patients unilaterally terminated their treatment relationships with the chiropractors. Because American Chiropractic failed to show that it has an objective, valid business expectancy with a probability of future economic benefit, the district court was correct to grant summary judgment to Trigon on this count.[18]

IV.

Count Eight

(Virginia Insurance Equality Statutes)

American Chiropractic also argues that the district court erred in dismissing its claim under the Virginia insurance equality laws for failure to state a claim. We

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[18] Because we conclude that American Chiropractic lacked a valid business expectancy, we do not address the district court's alternative ground for granting summary on this claim – that Trigon did not use improper means in interfering with the chiropractors' alleged business expectancy.

review the dismissal of a complaint under Federal Rule of Civil Procedure 12(b)(6) de novo. *Ostrzenski v. Seigel*, 177 F.3d 245, 251 (4th Cir. 1999). On appeal from an order granting a Rule 12(b)(6) motion to dismiss, this court accepts as true the facts as alleged in the complaint, views them in the light most favorable to the plaintiff, and recognizes that dismissal is inappropriate "unless it appears to a certainty that the plaintiff would be entitled to no relief under any state of facts which could be proved in support of his claim." *Mylan Lab., Inc. v. Matkari*, 7 F.3d 1130, 1134 n.4 (4th Cir. 1993); *see Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984) (explaining that dismissal for failure to state a claim is proper "only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations").

In its complaint, American Chiropractic alleged that Trigon violated Virginia's insurance equality laws, found in Va. Code Ann. §§ 38.2-2203, 38.2-3408, 38.2-4221, and 38.2-4312(E), because Trigon implemented reimbursement and utilization restrictions targeted only at chiropractors, not medical doctors. The district court found that none of these statutory provisions created private rights of action on their face and declined to read a private right of action into the sections.

As a preliminary note, §§ 38.2-2203, 38.2-4221 and 38.2-4312 do not apply to Trigon's business, so American Chiropractic cannot state a claim under those code sections. Section 38.2-2203 deals with "bodily injury liability insurance"; § 38.2-4221 applies to non-stock corporations; and § 38.2-4312(E) applies to health maintenance organizations. Trigon is a for-profit stock corporation that operates in the field of accident and sickness insurance. Thus, by their clear terms, these statutory provisions do not apply to Trigon's business decisions.

The issue is thus, whether § 38.2-3408, which applies to accident and sickness insurance companies, creates a private cause of action. For the following reasons, we hold that Virginia would not recognize a private cause of action under this code section. The section reads, in relevant part, "[i]f an accident and sickness insurance policy provides reimbursement for any service that may be legally performed by a person licensed in this Commonwealth as a chiropractor . . . reimbursement under the policy shall not be denied because the service is rendered by the licensed practitioner." Va. Code Ann. § 38.2-3408. The code section itself does not include an enforcement mechanism, but § 38.2-200 explains that the "[State Corporation] Commission is charged with the execution of all laws relating to insurance and insurers." Va. Code Ann. § 38.2-200. Section 38.2-221 grants the Commission the power to levy and enforce penalties against insurers for violations of the insurance code. Va. Code Ann. § 38.2-221. That section, however, also states that the "power and authority conferred upon the Commission by this section shall be in addition to and not in substitution for the power and authority conferred upon the courts by general law to impose civil penalties for violations of the laws of this Commonwealth." Va. Code Ann. § 38.2-221.

We have previously stated that "federal courts should be reluctant to read private rights of action into state laws where state courts and state legislatures have not done so. Without clear and specific evidence of legislative intent, the creation of a private right of action by a federal court abrogates both the prerogatives of the political branches and the obvious authority of states to sculpt the content of state law." *A & E Supply Co. v. Nationwide Mut. Fire Ins. Co.*, 798 F.2d 669, 674 (4th Cir. 1986). Applying this test, we held that the Virginia Unfair Trade Practices Act (UTPA) did not create a private cause of action because it lacked explicit language creating such an action. The Virginia UTPA

contained a statutory provision similar to § 38.2-221,[19] and we explained that it "[did] not create any new rights of action but instead preserve[d] any existing right of action that an injured person may have against a wrongdoer." *Id.* at 674 n.5. We have found no Virginia cases since *A & E Supply* that call this understanding into question.

Like the Virginia UTPA, § 38.2-3408 does not create a private right of action because it does not contain any specific statutory language creating such an action. The existence of § 38.2-221 does not evince a legislative intent to create private rights of action under the insurance code. Rather, as we explained in *A & E Supply*, that statutory provision only leaves in place pre-existing statutory and common-law rights of action.

Accordingly, the district court was correct in dismissing American Chiropractic's claim under the Virginia insurance equality laws.

~~V.~~

Count Three

(RICO)

American Chiropractic's final contention of error relating to the substantive holdings of the district court is that the district court erred in finding that its RICO claim was preempted by the McCarran-Ferguson Act and

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[19] The provision at issue in *A & E Supply* read that "no order of the Commission under this article shall in any way relieve or absolve any person affected by such order from any liability under any other laws of this Commonwealth." *A & E Supply Co. v. Nationwide Mut. Fire Ins. Co.*, 798 F.2d 669, 674 n.5 (4th Cir. 1986) (quoting Va. Code Ann. § 38.1-57.1)).

dismissing that claim pursuant to Rule 12(b)(6).[20] As stated above, we review de novo a complaint for failure to state a claim and "take all allegations as admitted and examine whether the plaintiff can prove any set of facts that would entitle him to relief." *Anderson v. Found. for Advancement, Educ. and Employment of Am. Indians*, 155 F.3d 500, 505 (4th Cir. 1998). "Federal 'notice' pleading standards require that the complaint be read liberally in favor of the plaintiff." *Id.* For the reasons that follow, we agree that American Chiropractic's claim is not preempted by the McCarran-Ferguson Act, but nonetheless affirm the district court's dismissal of this count because American Chiropractic failed to allege a claim for mail fraud or wire fraud and, accordingly, failed to state a claim for a RICO violation.

A.

The McCarran-Ferguson Act provides that "[n]o Act of Congress shall be construed to invalidate, impair, or supersede any law enacted by any State for the purpose of regulating the business of insurance." 15 U.S.C.A. § 1012(b) (West 1997). The McCarran-Ferguson Act does not apply to federal laws that are specifically targeted at the business of insurance. *Id.* Trigon argues that applying RICO to American Chiropractic's claims would invalidate, impair or supersede Virginia's insurance code, found at Title 38.2 of the Code of Virginia. For a federal law to be preempted by McCarran-Ferguson: (1) the state law in question must be enacted for the purpose of regulating the business of insurance; (2) the federal law must not be specifically related to the business of insurance; and (3) the federal law must invalidate, impair or supersede the state law in question. *Humana, Inc. v. Forsyth*, 525 U.S. 299, 307 (1999). The second

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[20] As discussed *infra*, in its RICO claim, American Chiropractic alleged that Trigon engaged in a pattern of racketeering activity including mail fraud, wire fraud, and extortion.

factor is easily satisfied because the Supreme Court has held that "RICO is not a law that specifically relates to the business of insurance." *Humana*, 525 U.S. at 307 (quotation marks omitted). Thus, we are left to decide whether Title 38.2 is a law enacted for the purpose of regulating the business of insurance and, if so, whether RICO impairs, invalidates or supersedes its operation.

We have little difficulty concluding that Title 38.2 is a set of laws enacted for the purpose of regulating the business of insurance. The Supreme Court has stated that "[s]tatutes aimed at protecting or regulating this relationship [between insurer and insured], directly or indirectly are laws regulating the 'business of insurance.'" *SEC v. Nat'l Securities, Inc.*, 393 U.S. 453, 460 (1969). "[T]he focus of McCarran-Ferguson is upon the relationship between the insurance company and its policyholders . . . ." *United States Dep't of Treasury v. Fabe*, 508 U.S. 491, 501 (1993). Accordingly, the McCarran-Ferguson Act encompasses "laws that possess the 'end, intention, or aim' of adjusting, managing, or controlling the business of insurance." *Id.* at 505. Applying these standards, Title 38.2 of the Code of Virginia, specifically §§ 38.2-200, 38.2-221 and 38.2-3408 at issue here, is a set of laws enacted for the purpose of regulating the business of insurance. Title 38.2 is limited to insurance companies and creates a comprehensive network of statutory provisions aimed at controlling and managing the business of insurance. For instance, § 38.2-3408, by requiring insurers to provide reimbursement for all providers of covered services, helps to manage the relationship between the policyholder and the insurance company by ensuring that if a particular service is covered by an insurance company, the policyholder can seek treatment from any provider able to perform that service.

Accordingly, we next must decide whether allowing a RICO claim to proceed against an insurance company would "invalidate, impair, or supersede" Virginia's insurance code. The Supreme Court recently considered a similar question: whether RICO invalidated, impaired or superseded Nevada's laws regulating insurance. *Humana*, 525 U.S. at 307. In *Humana*, the Court defined "invalidate" as "to render ineffective, generally without providing a replacement rule or law," and "supersede" as "to displace (and thus render ineffective) while providing a substitute rule." *Id.* Using these definitions, it is clear that, as in *Humana*, RICO's application would neither "invalidate" nor "supersede" Virginia law.[21]

Thus, the key question, as in *Humana*, is whether RICO's application to Trigon's alleged conduct would "impair" Virginia's law. In holding that RICO did not impair Nevada's law, the Supreme Court stated that

> When federal law does not directly conflict with state regulation, and when application of the federal law would not frustrate any declared state policy or interfere with a State's administrative regime, the McCarran-Ferguson Act does not preclude its application.

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[21] The district court relied heavily on *Ambrose v. Blue Cross & Blue Shield of Va., Inc.*, 891 F. Supp. 1153 (E.D. Va. 1995), *aff'd* 95 F.3d 41 (4th Cir. 1996) (unpublished per curiam opinion). Because *Ambrose* was decided before the Supreme Court's decision in *Humana, Inc. v. Forsyth*, 525 U.S. 299 (1999), and because the district court in *Ambrose* applied different definitions for the statutory terms than did the *Humana* Court, that decision is not helpful to our decision today.

Id. at 310. The only difference between the Nevada laws considered in *Humana* and the Virginia laws at issue in this case is that the Nevada laws explicitly provided for a private right of action, whereas the Virginia laws, as discussed *supra*, Part IV, do not. The district court found this difference dispositive, holding that application of RICO would convert Virginia's system of public redress into a federal system of private redress and thus that RICO would impair, invalidate, and supersede Virginia law. *Am. Chiropractic Ass'n*, 258 F. Supp. 2d at 735. We disagree.

Instead, we agree with the Tenth Circuit's resolution of this issue in *Bancoklahoma Mortgage Corp. v. Capital Title Co.*, 194 F.3d 1089 (10th Cir. 1999). The Missouri insurance laws at issue in that case, like the Virginia insurance laws at issue here, did not provide for a private right of action. The court nonetheless concluded that *Humana* compelled a holding that the RICO claims were not barred by the McCarran-Ferguson Act. *Id.* at 1099. The court held

> RICO "advances" Missouri's "interest in combating insurance fraud" and "does not frustrate any articulated [Missouri] policy." Although Missouri does not provide a private cause of action under its [insurance laws], it does allow causes of action under other state law. *See* Mo. Rev. Stat. § 375.944(4) (1991). Therefore, the McCarran-Ferguson Act does not bar [the] RICO claims.

Id. (quoting *Humana*, 525 U.S. at 314); *see also Humana*, 525 U.S. at 312 ("Moreover, the [Nevada] Act is not hermetically sealed; it does not exclude application of other state laws, statutory or decisional."); *Sabo v. Metropolitan Life Ins. Co.*, 137 F.3d 185 (3d Cir. 1998) (holding that RICO does not impair a state insurance law that permits private rights of action under other state laws). *But see LaBarre v. Credit*

Acceptance Corp., 175 F.3d 640 (8th Cir. 1999) (holding that the lack of a private right of action in the state insurance laws was dispositive without considering whether the statute at issue permitted the application of other state laws to the conduct of insurers).

RICO furthers Virginia's interest in policing insurance fraud and misconduct and does not frustrate any declared state policy. Although RICO's damage provisions are admittedly more severe than many state laws, RICO does not interfere with Virginia's administrative scheme. Moreover, as discussed in Part IV, although Virginia's insurance laws do not create private rights of action, § 38.2-221 allows for other state laws to apply to the conduct of insurers.[22] Va. Code Ann. § 38.2-221 (The "power and authority conferred upon the Commission by this section shall be in addition to and not in substitution for the power and authority conferred upon the courts by general law to impose ~~civil~~ penalties for violations of the laws of this Commonwealth."). We agree with the Tenth Circuit that in such a situation, *Humana* compels a conclusion that American Chiropractic's RICO claim was not barred by the McCarran-Ferguson Act.

B.

Although we disagree with the reasoning of the district court, we can affirm the dismissal of the complaint "on any basis fairly supported by the record." *Eisenberg v. Wachovia Bank, N.H.*, 301 F.3d 220, 222 (4th Cir. 2002). Perhaps anticipating our conclusion in Part V.A., Trigon has argued in the alternative that we should affirm the 12(b)(6)

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[22] For example, in this case American Chiropractic asserted state law claims for tortious interference with a business relationship, common law and statutory conspiracy, and breach of contract.

dismissal of the RICO claim because American Chiropractic has failed to state a claim under RICO. RICO provides, in pertinent part, that "[i]t shall be unlawful for any person who has received any income derived, directly or indirectly, from a pattern of racketeering activity . . . to use or invest, directly or indirectly, any part of such income, or the proceeds of such income . . . [in] the establishment or operation of, any enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce." 18 U.S.C.A. § 1962(a). "Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue . . . and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee." 18 U.S.C.A. § 1964(c).

A plaintiff bringing a civil RICO action under § 1964(c) must adequately plead at least two predicate acts of racketeering that form a "pattern of racketeering." 18 U.S.C.A. § 1961(5). Private civil RICO suits may be brought regardless of whether the government chooses to prosecute the criminal RICO violation. *Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 493 (1985). Here, American Chiropractic's complaint stated that Trigon committed mail fraud, wire fraud, and extortion.[23] All three qualify as "racketeering activity," *see* 18 U.S.C.A. § 1961(1), but Trigon contends that American Chiropractic cannot state a claim for any of those predicate acts.

We consider first the alleged mail and wire fraud. The federal mail and wire fraud statutes prohibit the use of the mails or interstate wires in furtherance of schemes to defraud. 18 U.S.C.A. §§ 1341, 1343 (West 2000). For the

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[23] American Chiropractic also alleged the predicate act of securities fraud in its complaint, but it did not pursue that claim because Trigon previously had not been convicted of securities fraud, as required by 18 U.S.C.A. § 1964(c) (West 2000).

government to obtain a conviction for mail or wire fraud it must prove (1) a scheme disclosing an intent to defraud; and (2) the use, respectively, of the mails or interstate wires in furtherance of the scheme. *See Chisolm v. Transouth Fin. Corp.*, 95 F.3d 331, 336 (4th Cir. 1996). In a prosecution for mail or wire fraud, the government is not required to show reliance on any misrepresentation.

To recover civil RICO damages, however, an individual must also allege that he was injured "by reason of" the pattern of racketeering activity. *Id.*; *see also* 18 U.S.C.A. § 1964(c). To meet this burden with respect to mail fraud and wire fraud, a plaintiff must "*plausibly* allege both that [he] detrimentally relied in some way on the fraudulent mailing [or wire] . . . and that the mailing [or wire] was a proximate cause of the alleged injury to [his] business or property." *Chisolm*, 95 F.3d at 337 (emphasis added). The alleged fraud "must be a 'classic' one[,] . . . the plaintiff must have justifiably relied, to his detriment, on the defendant's material misrepresentation." *Id.* American Chiropractic's complaint states that Trigon committed mail and wire fraud by representing, in its "Ancillary Professional Provider Agreement," that it reimburses healthcare providers pursuant to the Federal Resource Based Relative Value Scale (RBRVS).[24] The complaint stated that chiropractors justifiably relied upon this alleged misrepresentation in deciding to enter into provider agreements with Trigon and that the chiropractors were injured because Trigon does not, in fact, reimburse chiropractic services pursuant to the

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[24] The RBRVS is the relative value scale used by Medicare in setting its reimbursement rates for providers under that program..

RBRVS.[25] Trigon entered the Ancillary Professional Provider Agreement in full to support its motion to dismiss.

Although as a general rule extrinsic evidence should not be considered at the 12(b)(6) stage, we have held that when a defendant attaches a document to its motion to dismiss, "a court may consider it in determining whether to dismiss the complaint [if] it was integral to and explicitly relied on in the complaint and [if] the plaintiffs do not challenge its authenticity." *Phillips v. LCI Int'l Inc.*, 190 F.3d 609, 618 (4th Cir. 1999); *see also Parrino v. FHP, Inc.*, 146 F.3d 699, 705-06 (9th Cir.1998). As the Third Circuit has explained

> The rationale underlying this exception is that the primary problem raised by looking to documents outside the complaint—lack of notice to the plaintiff—is dissipated "[w]here plaintiff has actual notice . . . and has relied upon these documents in framing the complaint." What the rule seeks to prevent is the situation in which a plaintiff is able to maintain a claim of fraud by extracting an isolated statement from a document and placing it in the complaint, even though if the statement were examined in the full context of the document, it would be clear that the statement was not fraudulent.

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[25] At oral argument before this court, counsel for American Chiropractic also alleged that Trigon committed mail fraud by telling its plan enrollees that healthcare providers were reimbursed in accordance with Medicare rates. The district court previously had held that American Chiropractic lacked standing to advance the claims of individual patients, and American Chiropractic did not appeal that ruling. Thus, the argument that Trigon committed mail fraud against its enrollees is not properly before this court.

In re Burlington Coat Factory Securities Litigation, 114 F.3d 1410, 1426 (3d Cir. 1997) (quotation marks omitted).

As stated above, American Chiropractic explicitly referred to the Ancillary Professional Provider Agreement, and its mail and wire fraud claims are based on the alleged misrepresentation made in that document. In addition, American Chiropractic does not contest the authenticity of the documents. Accordingly, we can consider those documents at the 12(b)(6) stage of the litigation. The Ancillary Professional Provider Agreement states, in part, that "[m]ost Trigon fees are based upon external benchmarks of relative value, for example, the [RBRVS]." (J.A. at 156.) Thus, American Chiropractic alleges, Trigon has misled chiropractors into believing that their reimbursement would be based upon Medicare's reimbursement system. In full, however, the Ancillary Professional Provider Agreement states that

> *Trigon's fee schedules represent the maximum Allowable Charge for each covered service that corresponds to a single service code.* The preponderance of valid service codes [are] from Current Procedural Terminology (CPT), HCFA Common Procedural Coding System (HCPCS), American Dental Association (ADA), or National Drug Codes (NDC). For *covered services represented by a single code, the maximum Allowable Charge is the fee schedule amount determined by Trigon in its sole discretion* or your usual charge for the service, whichever is less. *Most Trigon fees are based upon external benchmarks* or relative value, for example, the Federal Resource Based Relative Value Scale (RBRVS), Average Wholesale Price (AWP), American Society of Anesthesiologists (ASA), relative value and

> Medicare's laboratory and Durable Medical Equipment (DME) fees.

(J.A. at 156 (footnote omitted) (emphases added).)

The Agreement comes with Trigon's fee schedule attached. Relevant here, Trigon's fee schedule includes the maximum allowable charge for the four service codes associated with spinal manipulations. The fee schedule discloses that Trigon reimburses providers who perform spinal manipulations the same amount regardless of how many "regions" of the spine are manipulated. The RBRVS, however, provides a higher reimbursement when more spinal regions are manipulated. It is undisputed that Trigon began this reimbursement practice in 1997.

We conclude that American Chiropractic, as a matter of law, could not justifiably rely on the statement that "most" Trigon fees are based on the RBRVS for two reasons. First, the statement only provides that "*most*" fees are based on the external benchmark of the RBRVS. The term "most" indicates that some of Trigon's reimbursement payments were not based upon the RBRVS. Second, the remainder of the document clearly explains that Trigon's fee schedule represents the maximum allowable charge for a service. Moreover, the fee schedule discloses that Trigon does not follow the RBRVS when reimbursing for spinal manipulations. Because the fee schedule discloses that Trigon does not reimburse for spinal manipulation services according to the RBRVS, American Chiropractic could not have justifiably relied on Trigon's alleged misrepresentation that most of Trigon's fees were based on the RBRVS. Accordingly, American Chiropractic has failed to plausibly allege that it justifiably relied on a misrepresentation by Trigon.

To withstand a motion to dismiss for failure to state a RICO claim, a plaintiff must plausibly allege at least two predicate acts of racketeering. As noted above, American Chiropractic's complaint alleged three predicate acts – mail fraud, wire fraud, and extortion. Because we have held that American Chiropractic failed to state a claim for mail or wire fraud, it has failed to allege at least two predicate acts of racketeering, and we need not address whether it properly alleged a claim of extortion.

Although, in light of *Humana, Inc v. Forsyth*, American Chiropractic's claim is not preempted by the McCarran-Ferguson Act, we affirm the dismissal of this count because American Chiropractic failed to state a claim for a RICO violation.

VI.

Finally, American Chiropractic argues that the district court abused its discretion in handling discovery in this case by refusing to extend the temporal scope of discovery to include events prior to 1996 and by failing to lengthen discovery after Trigon turned over documents relating to the MCAP in a tardy manner.[26] "We afford substantial discretion to a district court in managing

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[26] American Chiropractic raises four other arguments relating to the conduct of discovery. Those arguments are that the district court abused its discretion by: (1) failing to require Trigon to produce the identity of all medical doctors employed by Trigon; (2) refusing to compel Trigon to turn over information regarding any service code that paid a lower reimbursement amount to limited-license practitioners than to medical doctors; (3) by refusing to compel Trigon to turn over more of Dr. Colley's file; and (4) by refusing to allow American Chiropractic to conduct another Rule 30(b)(6) deposition. We have examined these issues carefully and conclude that they are without merit; thus, we affirm those rulings as well.

discovery and review discovery rulings only for abuse of that discretion." *United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 290 (4th Cir. 2002), *cert. denied*, 123 S. Ct. 1929 (2003).

Discovery commenced in September 2001, soon after the district court addressed Trigon's motion to dismiss, and the parties agreed in writing to limit discovery requests to events occurring after January 1, 1996.[27] Discovery lasted ten months, concluding on June 28, 2002. On June 14, 2002, just prior to the close of discovery, Trigon turned over documents relating to Dr. Colley and his involvement with the MCAP. Trigon admitted that despite its efforts to locate the documents, they had been "overlooked" and offered to cure the late production by allowing American Chiropractic to depose Dr. Colley after the stated discovery deadline passed. Trigon also permitted American Chiropractic to depose two representatives of medical societies with members on the MCAP after the close of discovery.

American Chiropractic's first assertion is that the district court abused its discretion by limiting the scope of discoverable materials to those created after January 1, 1996. By doing so, American Chiropractic contends, the district court rendered American Chiropractic unable to pursue key avenues of investigation in the case, including the $500 coverage cap instituted in 1988 and the MCAP meeting from October of 1995 where the Low Back Guideline was approved. Unfortunately for American Chiropractic, this limitation was imposed not by judicial fiat, but by the mutual agreement of the parties. The record shows that American Chiropractic and Trigon agreed, in writing, to limit discovery to events arising after January 1, 1996 unless,

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[27] The parties agreed that this time limit could be revised by negotiations in good faith if American Chiropractic could show a valid basis for requesting additional information.

in good faith, a more expansive time period was necessary. American Chiropractic failed to contact Trigon to discuss expanding the time period and did not mention the limiting nature of the agreement to the district court until June 18, 2002, a mere ten days before the close of discovery. The district court found that expanding the time period to events before January 1, 1996, would be "overly burdensome" to Trigon and refused American Chiropractic's invitation to do so. (J.A. at 1137.) We cannot say the district court abused its discretion by refusing, at such a late date, to expand the scope of discovery beyond that mutually agreed to by the parties.

Next, American Chiropractic contends that the district court abused its discretion by refusing to extend the end-date of discovery when Trigon turned over documents relating to the Low Back Guideline and the MCAP's October 25, 1995 meeting just before the close of discovery. Trigon does not dispute that it was dilatory in turning over those particular documents; in a letter to American Chiropractic, it admitted that "despite Trigon's good faith efforts to produce all of the relevant documents, these documents were not found and were overlooked during the previous document productions. This was admittedly a mistake by Trigon." (J.A. at 5296.) Despite this admitted mistake, the district court denied American Chiropractic's request for more discovery and found that "any mistakes on Trigon's part have not caused prejudice." (J.A. at 1131.)

While we are not sure that Trigon's late production of these documents did not have the potential to cause prejudice, two factors lead us to conclude that the district court did not abuse its discretion in refusing to extend discovery. First, Trigon offered to cure the late production by allowing American Chiropractic to conduct an additional deposition of Dr. Colley after the close of discovery. Second, Trigon allowed American Chiropractic to take depositions

of two of the medical societies with members on the MCAP after the close of discovery as well.

Additionally, if American Chiropractic felt that it had insufficient time to conduct discovery given the late production of documents, and/or that Trigon was not negotiating in good faith an agreement for further discovery, it could have filed a Rule 56(f) motion in response to Trigon's motion for summary judgment.[28] We have held that "[i]f a party believes that more discovery is necessary for it to demonstrate a genuine issue of material fact, the proper course is to file a Rule 56(f) affidavit." *Harrods Ltd. v. Sixty Internet Domain Names*, 302 F.3d 214, 244 (4th Cir. 2002). This American Chiropractic did not do. In sum, we find that the district court did not abuse its discretion in its discovery rulings.

VII.

In conclusion, we affirm the district court's grant of summary judgment on American Chiropractic's § 1 Sherman Act claim, Virginia civil and common law conspiracy claims, and tortious interference claim. We also affirm the district court's dismissal of American Chiropractic's claim under the Virginia insurance equality laws for failure to state a claim. Although we disagree with the district court's holding that American Chiropractic's RICO claim is preempted by the McCarran-Ferguson Act, we affirm the district court's dismissal of that claim because American Chiropractic has failed to state a claim for a RICO

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[28] Federal Rule of Civil Procedure 56(f) provides that "[s]hould it appear from the affidavits of a party opposing [a summary judgment] motion that the party cannot for reasons stated present by affidavits facts essential to justify the party's opposition, the court may . . . order a continuance to permit . . . discovery to be had."

violation. We also find that the district court's discovery rulings were not an abuse of discretion.

AFFIRMED

PUBLISHED

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

AMERICAN CHIROPRACTIC ASSOCIATION, ET AL.,

Plaintiffs,

v.

TRIGON HEALTHCARE, INC., ET AL.,

Defendants.

Case No. 1:00CV00113

OPINION

By: James P. Jones
United States District Judge

[ENTERED: APRIL 25, 2003]

George P. McAndrews, McAndrews, Held & Malloy, Ltd., Chicago, Illinois, for Plaintiffs; Howard Feller, McGuireWoods LLP, Richmond, Virginia, for Defendants.

American Chiropractic Association, Inc., Virginia Chiropractic Association, Inc., and certain individual doctors and patients of chiropractic medicine filed this action against health insurer Trigon Healthcare, Inc., and affiliated companies ("Trigon") claiming anticompetitive activities harmful to chiropractic medicine. Following discovery, Trigon has moved for summary judgment. For the reasons set forth in this opinion, I find that there are no genuine issues of material fact remaining for trial and that Trigon is entitled to judgment in its favor.

I

Chiropractic is a recognized branch of the healing arts, and chiropractic treatment is widely utilized by consumers of medical services, mainly for neuromusculoskeletal disorders such as back pain, neck pain, and headaches. Such disorders affect a large proportion of the American adult population.[1] Trigon is a health care insurer that does business as Trigon Blue Cross Blue Shield and was formerly known as Blue Cross and Blue Shield of Virginia.[2] Until 1991 Trigon was a not-for-profit entity, but thereafter became a for-profit, publically owned corporation, in the business of offering individual and group healthcare plans to its subscribers. It is currently "the largest managed healthcare company in Virginia."[3]

The core claim made in this case is that Trigon has intentionally prevented or discouraged its subscribers from utilizing chiropractic at the behest of physicians. In the plaintiffs' words, the purpose of this conspiracy was "to

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[1] *See* U.S. Dep't of Health & Human Servs., Office of Inspector Gen., *Chiropractic Care: Controls Used By Medicare, Medicaid, and Other Payors* 1 (1998), Pls.' Ex. 6. Most chiropractic treatment consists of manual adjustments of the spine in order to correct abnormalities known as subluxations. *See* Third Am. Comp. ¶ 39-41.

[2] Trigon is an independent licensee of Blue Cross and Blue Shield Association ("BCBSA"). BCBSA was initially named as a party to this action but was voluntarily dismissed as a defendant by the plaintiffs. Trigon was recently acquired by a larger healthcare company, Anthem, Inc., based in Indiana. *See* Bob Rayner, *Trigon, Anthem Deal Gets OK*, Richmond Times-Dispatch, July 24, 2002, at C1.

[3] *See* Third Am. Comp. ¶ 67; Answer to Third Am. Comp. ¶ 67.

prevent the transfer of insurance dollars from medical doctors to chiropractors."[4] More specifically, the plaintiffs contend that Trigon's anticompetitive conduct included the issuance of a clinical practice guideline on the treatment of low back pain; the continuation of a $500 reimbursement cap on spinal manipulations; the reduction in the payment rate for services other than spinal manipulations; the "leveling" of payments for manipulations of multiple regions of the spine; suggesting to competing providers—osteopaths and physical therapists—ways to avoid payment limitations; and negotiation with medical doctors rather than chiropractors over reimbursement terms. The legal foundations for the plaintiffs' claims are the anticonspiracy provisions of the Sherman Act, 15 U.S.C.A. § 1 (West 1997) (Count I), the Virginia Civil Conspiracy Act, Va. Code Ann. §§ 18.2-499, -500 (Michie 1996) (Count V), and the common law (Count VII); the antimonopolization provision of the Sherman Act, 15 U.S.C.A. § 2 (West 1997) (Count II); tortious interference with business expectancies (Count IV); and breach of contract (Count VI).[5] The court has jurisdiction pursuant to 28 U.S.C.A. §§ 1331, 1337(a), and 1367(a) (West 1993 & Supp. 2002).

Following extensive discovery, Trigon has moved for summary judgment. The issues have been briefed and argued and the motion is ripe for decision.

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[4] Pls.' Opp'n 14.

[5] Counts III (RICO) and VIII (state insurance equality laws) were earlier dismissed on motion of the defendants. *See Am. Chiropractic Ass'n. v. Trigon Healthcare, Inc.*, 151 F. Supp. 2d 723, 732-35 (W.D. Va. 2001).

II

Summary judgment is appropriate when there is "no genuine issue of material fact," given the parties' burdens of proof at trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *see* Fed. R. Civ. P. 56(c). In determining whether the moving party has shown that there is no genuine issue of material fact, a court must assess the factual evidence and all inferences to be drawn therefrom in the light most favorable to the non-moving party. *See Ross v. Communications Satellite Corp.*, 759 F.2d 355, 364 (4th Cir. 1985).

Rule 56 "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Summary judgment is not "a disfavored procedural shortcut," but an important mechanism for weeding out "claims and defenses [that] have no factual basis." *Id.* at 327.

It is equally well established that summary judgment is appropriate in cases alleging an antitrust conspiracy and indeed is required when the plaintiff fails to offer "specific facts showing that there is a genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). "'[T]he very nature of antitrust litigation encourages summary disposition of such cases when permissible." *Oksanen v. Page Mem'l Hosp.*, 945 F.2d 696, 708 (4th Cir. 1991) (quoting *Collins v. Associated Pathologists, Ltd.*, 844 F.2d 473, 475 (7th Cir. 1988)).

After careful review of the summary judgment record, I find that the intracorporate immunity doctrine bars the majority of the plaintiffs' conspiracy allegations in this case because Trigon, as a matter of law, cannot conspire

with its employees and agents. For the remainder of the plaintiffs' allegations, Trigon's sworn denials of conspiracy, the affidavits, and the deposition testimony establish that Trigon acted unilaterally and that there is no basis for any inference of a conspiracy. Accordingly, summary judgment is warranted on the antitrust conspiracy claims.

A

Section 1 of the Sherman Act prohibits unreasonable restraints of trade effected by "contract, combination . . . or conspiracy." 15 U.S.C.A. § 1. "It is incontestable that 'concerted action' in restraint of trade lies at the heart of a Sherman Act section 1 violation." *Va. Vermiculite, Ltd. v. Historic Green Springs, Inc.*, 307 F.3d 277, 280 (4th Cir. 2002). "The Sherman Act distinguishes between concerted and independent action." *Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139,145 (4th Cir. 1990). Thus, unless the plaintiffs can prove that Trigon conspired with one or more other persons, Trigon's policies and practices regarding chiropractors cannot be a violation of section 1 of the Sherman Act.

"The doctrine of intracorporate immunity holds that because at least two persons must be present to form a conspiracy, a corporation cannot conspire with itself. " *Am. Chiropractic Ass'n v. Trigon Healthcare, Inc.*, 151 F. Supp. 2d at 731. A corporation cannot conspire with its employees or agents because "[t]he officers of a single firm are not separate economic actors pursuing separate economic interests, so agreements among them do not suddenly bring together economic power that was previously pursuing divergent goals." *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 769 (1984).

There is a limited exception to the general rule that a corporation cannot conspire with its employees or agents when these individuals have "an independent personal stake in achieving the corporation's illegal objective." *Oksanen*, 945 F.2d at 705.

The plaintiffs have identified the primary coconspirators with Trigon as the medical doctors who served on Trigon's Managed Care Advisory Panel, the medical associations with which they were affiliated, the Medical Society of Virginia, and osteopaths and physical therapists.[6] In one of their principal arguments, the plaintiffs claim that the doctors on the Managed Care Advisory Panel helped establish a clinical practice guideline on the treatment of low back pain that de-emphasized the importance of spinal manipulation.

Despite these allegations, the summary judgment record shows that the independent personal stake exception is inapplicable and that intracorporate immunity bars the bulk of the conspiracy claims. In the first place, the Trigon employees who are alleged to be conspirators were full-time officers and employees of Trigon, did not engage in the

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[6] In their Complaint, the plaintiffs contended that the coconspirators were medical doctors serving on Trigon's Provider Policy Committee and BCBSA. *See* Third Am. Comp. ¶¶ 126, 127, 133. The Provider Policy Committee (formerly named the Provider Relations Committee) was an ad hoc committee of Trigon's board of directors, while the Managed Care Advisory Panel contained other membership. Trigon objects to any consideration of allegations concerning conspirators not expressly identified in the Complaint, but the federal rules provide that the pleadings may be deemed amended to conform to the evidence. *See* Fed. R. Civ. P. 15(b). The defendants have been made aware of the actual contention of the plaintiffs through the extensive discovery in this case. Accordingly, there is no prejudice to any party in considering these additional allegations.

private practice of medicine, always acted in Trigon's best interest, and did not obtain any personal benefit from Trigon's decisions regarding chiropractors.

Second, the plaintiffs have not presented any evidence to show that any of the Trigon panel members competed with them for the treatment of neuromusculoskeletal disorders. At most, the plaintiffs showed that some of the doctor members were designated by their professional organizations.[7] The plaintiffs' contention that other members of these entitles may compete with doctors of chiropractic is unavailing absent evidence that Trigon's agents—the members of the Managed Care Advisory Panel—derived some direct economic benefit from the alleged illegal conduct. *See Oksanen*, 945 F.2d at 705.

Finally, it is established in the record that the Managed Care Advisory Panel had no decision making authority, but acted in an advisory capacity to Trigon. As such, its members could not control Trigon's decisions. *See id.* ("'To give advice when asked by the decisionmaker is not equivalent to being the decisionmaker itself.'") (quoting

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[7] While Trigon formally appointed the members of the Managed Care Advisory Panel, there is evidence that in practice members were chosen by the Virginia chapters of the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Physicians, and the American College of Surgeons, along with the Virginia Society of Internal Medicine, the Virginia Obstetrical and Gynecological Society, the Medical Society of Virginia, the University of Virginia Medical School, Eastern Virginia Medical School, and the Medical College of Virginia. *See* Letter from J. Lawrence Colley to Craig N. Bush of 5/2/97, Pls.' Ex. 27. As its name implies, the purpose of the Managed Care Advisory Panel was to advise Trigon on clinical issues related to managed care plans. *See* Norwood Dep. ¶ 6, Defs.' Ex. 7.

Penn. Dental Ass'n v. Medical Serv. Ass'n, 745 F.2d 248, 259 (3d Cir. 1984)).

B

The plaintiffs' remaining allegations are that Trigon conspired with the BCBSA and the professional organizations that had representatives on the Managed Care Advisory Panel to restrict access to chiropractors. However, the record demonstrates that no conspiracy existed.

The Supreme Court has declared that to establish the existence of concerted action, a plaintiff must prove that two or more persons possessed "a unity of purpose or a common design and understanding, or a meeting of minds in an unlawful arrangement." *Am. Tobacco Co. v. United States*, 328 U.S. 781, 810 (1946). "[T]here must be direct or circumstantial evidence that reasonably tends to prove that [the parties] had a conscious commitment to a common scheme designed to achieve an unlawful objective." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 768 (1984).

Where, as here, the allegations of an antitrust conspiracy are based on circumstantial evidence,[8] the Supreme Court has set forth the standard for what

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[8] In spite of the plaintiffs' argument to the contrary, there is no direct evidence in the record of a conspiracy. *See In re Baby Food Antitrust Litig.*, 166 F.3d 112, 118 (3d Cir. 1999) (holding that direct evidence must be "explicit and requires no inferences to establish the proposition or conclusion being asserted."). "Only rarely will there be direct evidence of an express agreement" in conspiracy cases. *Local Union No. 189, Amalgamated Meat Cutters v. Jewel Tea Co.*, 381 U.S. 676, 720 (1965) (Goldberg, J., dissenting). All of the alleged conspirators in this case expressly deny any plans or discussions concerning the object of the alleged conspiracy.

constitutes sufficient evidence of a conspiracy and has limited the range of permissible inferences that can be drawn from circumstantial evidence. "The correct standard is that there must be evidence that tends to exclude the possibility of independent action by the [defendants]." *Monsanto*, 465 U.S. at 768. "To survive a motion for summary judgment . . . a plaintiff seeking damages for a violation of § 1 must present evidence 'that tends to exclude the possibility' that the alleged conspirators acted independently." *Matsushita Elec. Indus. Co.*, 475 U.S. at 588.

At bottom, the plaintiffs' conspiracy argument makes no economic sense. Trigon, as a profit-seeking corporation, had no economic motive to prevent referrals to chiropractors. In fact, the uncontradicted evidence in the record is that from 1996 to 2001 the number of chiropractors in Trigon's Participating Provider ("PAR") and Preferred Provider Organization ("PPO") networks nearly doubled (from 1095 to 1934),[9] the number of Trigon insureds receiving chiropractic manipulations nearly trebled (from 26,275 to 74,477),[10] and chiropractors' share of Trigon's total payments to professional providers increased by fourteen percent.[11] Trigon's profit-maximizing interest was to allow its members to obtain needed medical care while paying medical providers the lowest possible cost. If, as the plaintiffs' believe, chiropractic treatments are cheaper and more effective than certain competing medical remedies (such as drug therapies), it was clearly economically advantageous to Trigon to encourage, rather than

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[9] *See* Bradley Aff., Defs.' Ex. 39. The number of licensed chiropractors in Virginia increased by only eighteen percent in that period. *See* Third Am. Comp. ¶ 47.

[10] *See* Zeh Aff., Defs.' Ex. 1.

[11] *See* Bean Aff., Defs.' Ex. 2.

discourage, the utilization of chiropractic. Moreover, to the extent potential subscribers desired chiropractic care, it was in Trigon's competitive interest to provide access to that treatment. The fact that Trigon did not increase the use of chiropractic treatment as much as the plaintiffs desire is not evidence of conspiracy.[12]

In addition, the specific alleged anticompetitive conduct complained of by the plaintiffs does not support the existence of an unlawful conspiracy.

For example, the plaintiffs rely heavily on Trigon's adoption of a clinical practice guideline in 1996 as proof of a conspiracy. This guideline, entitled "Managing Low Back Problems in Adults," was drafted by Trigon employees and considered (but not revised) by the Managed Care Advisory Panel. Trigon contends that its guideline, which was distributed to all of its providers including chiropractors, was merely a simplified version of a clinical guideline published by a federal agency in 1994.[13] The plaintiffs point to the opinion of their expert, Scott Haldeman, that the

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[12] The plaintiffs argue that Trigon's statistics also show that the number of visits per patient and payments per patient decreased over time. *See* Pls.' Opp'n 46-49. However, as the defendants point out, that may be more a function of patients' decisions following initial referrals.

[13] *See* U.S. Dep't of Health & Human Servs., Public Health Serv., Agency for Health Care Policy & Research, *Clinical Practice Guideline No. 14, Acute Low Back Problems in Adults* (1994), Pls.' Ex. 22. In addition, there is a companion "Quick Reference Guide for Clinicians" that contains the highlights of the guideline, including algorithms (step-by-step procedures) for evaluating low back pain. *See* Pls.' Ex. 23. Trigon's algorithms contained in its guideline closely follow the federal algorithms. *See* Side-by-Side Comparison of AHCPR Guidelines & Trigon Guidelines, Defs.' Ex. 51.

Trigon guideline is "inconsistent" and "in conflict" with the federal guideline, mainly because while the Trigon guideline recommends "manipulation" as a treatment option, it omits the federal definition of manipulation. The expert believes that the federal definition favors the type of manipulation given by chiropractors over other providers.[14] Even assuming that this opinion is credible—and I find it very thin—it is insufficient circumstantial proof of a conspiracy. It is clear that Trigon's guideline follows the federal guideline in a highly abbreviated form. The uncontested evidence is that since Trigon's guideline was issued in 1996, no chiropractor provider ever complained to Trigon about the omission of the definition of manipulation or anything else about it. Moreover, since it was issued, use of chiropractic treatment by Trigon subscribers has substantially increased.

The plaintiffs also complain that the continuation by Trigon in its health care plans of a maximum annual payment allowance of $500 for "spinal manipulations and other manual medical interventions"[15] is evidence of a conspiracy with medical doctors and their organizations. Again, however, this fact supports the proposition that Trigon acted in its own self interest to limit its costs. The evidence shows that Trigon's payment and coverage policies were based on its understandable goal of obtaining

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[14] *See* Haldeman Decl. ¶¶ 4, 5, Pls.' Ex. 24. In the federal guideline manipulation is defined as "manual therapy in which loads are applied to the spine using short or long lever methods." U.S. Dep't of Health & Human Servs., *supra* note 12, at 34. Both the Trigon and the federal guidelines recommend manipulation as a treatment option for nonspecific low back symptoms, but the Trigon guideline does not define manipulation.

[15] Third Am. Comp. ¶ 119.

professional services at the lowest possible cost the market would bear.

Trigon was not alone in its utilization of mechanisms for limiting the expense of chiropractic services. The summary judgment record shows that caps on chiropractic payments were used by ninety-four percent of selected large national private insurers,[16] and that other healthcare insurers in Virginia have practices comparable to Trigon's.[17] There is no question but that the intent of these methods was to limit the quantity of chiropractic care. But that is not proof that Trigon (or other insurers) conspired with the medical profession to this end.[18]

The plaintiffs submitted evidence that Trigon "suggested" to osteopaths and physical therapists ways to "get around" the limitations on manipulation reimbursement and that since those professions are "closely associated with" medical doctors, these efforts show evidence of the charged conspiracy.[19] Trigon denies any such suggestions; in any event, the record is clear that Trigon never changed its procedures to benefit osteopaths or physical therapists. I do not find these allegations

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[16] *See* U.S. Dep't of Health & Human Servs., *supra* note 1, at 6. Other methods used to control chiropractic costs are requiring physician referrals; co-payments, coinsurance, and deductibles; and prepayment reviews. *See id.* at ii.

[17] *See* Bowles Aff., Defs.' Ex. 31.

[18] For the same reasons, Trigon's 1996 reduction of the reimbursement rate for nonmanipulative procedures by chiropractors and its 1997 "leveling" of payments to chiropractors for manipulations of various regions of the spine, are not proof of a conspiracy.

[19] Pls.' Opp'n 38, 41.

sufficient to produce a triable issue of fact as to the existence of an anticompetitive conspiracy.

Finally, the plaintiffs contend that there is evidence that Trigon negotiated with the Medical Society of Virginia, representing medical doctors, over reimbursement terms, but did not similarly negotiate with chiropractors. However, I agree with the defendants that the evidence shows only that Trigon was willing to listen to suggestions by this physician group. Of course, there is no evidence in the record that Trigon ever discussed with the Medical Society of Virginia, or any other professional association, any policies harmful to chiropractic providers.

C

The plaintiffs allege in Count II that Trigon has attempted to monopolize the market for the treatment of neuromusculoskeletal disorders in violation of section 2 of the Sherman Act. They also allege that Trigon has conspired with BCBSA and medical doctors to monopolize this market. The plaintiffs' conspiracy to monopolize claim under section 2 of the Sherman Act fails for the same reason that the plaintiffs' section 1 claim fails—there is no evidence of a conspiracy between Trigon and any other persons.

The attempt to monopolize claim also is defective. This claim has four essential elements: (1) a specific intent to monopolize; (2) a relevant market; (3) predatory or anticompetitive acts; and (4) a dangerous probability of success in achieving monopolization. *See Advanced Health-Care Servs., Inc.*, 910 F.2d at 147. The short answer to this claim is that Trigon and chiropractors do not compete in the same market. *See White v. Rockingham Radiologists, Ltd.*, 820 F.2d 98, 104 (4th Cir. 1987) ("One who does not compete in a product market or conspire with a competitor cannot be held liable as a monopolist in that market.").

D

The plaintiffs' state law conspiracy claims (Count V and Count VII) fail for the same reasons as the antitrust claims. Virginia has adopted the intracorporate immunity doctrine. *See Selman v. Am. Sports Underwriters, Inc.*, 697 F. Supp. 225, 238 (W.D. Va. 1988). For those alleged conspirators not subject to the doctrine of intracorporate immunity, the facts as recited in connection with the federal antitrust laws equally show that no violation of the Virginia conspiracy laws has occurred.

III

The plaintiffs also raise other state law claims, of which the court has supplemental jurisdiction. While I might dismiss these pendant claims, considerations of economy and fairness indicate that I should adjudicate them, since they have been fully developed and presented in this case. *See Carnegie-Mellon Univ. v. Cohill*, 484 U.S. 343, 357 (1988).

The chiropractor plaintiffs claim that Trigon interfered by improper means with their business expectancies to treat patients covered by Trigon. The requisite elements for proof of a tortious interference are: (1) the existence of a valid business expectancy; (2) knowledge of the expectancy on the part of the interferor; (3) an intentional interference by improper methods; and (4) resultant damage to the party whose relationship or expectancy has been disrupted. *See Duggin v. Adams*, 360 S.E.2d 832, 835-36 (Va. 1987). I find that there is insufficient evidence that any such valid expectancy existed or, if it did, that any improper means of interference was used by Trigon. As explained above, Trigon's efforts to limit its costs were not illegal and do not support the state law tort claim.

Similarly, there is no evidence that Trigon breached any contract with the plaintiffs. The evidence does not support any claim that Trigon's reimbursement payments were unconscionable. *See Reibold v. Simon Aerials, Inc.*, 859 F. Supp. 193, 198 (E.D. Va. 1994) ("Courts will rarely find unconscionable contracts arising in a commercial context."). As noted earlier, Trigon's limitations on treatment by chiropractors are not unusual in the healthcare field. *See Stedor Enters., Ltd. v. Armtex, Inc.*, 947 F.2d 727, 733 (4th Cir. 1991) (holding that where disputed provision of commercial contract was common to industry, a finding of unconscionability cannot be based on disparate size of parties). Moreover, there is no evidence that the chiropractors were under legal duress when they accepted the terms of their provider agreements. *See Blevins v. New Holland N. Am., Inc.*, 97 F. Supp. 2d 747, 751 (W.D. Va. 2000) (holding that lack of opportunity to negotiate a provision of a commercial contract is not sufficient evidence of unconscionability).

For these reasons, the plaintiffs are unable to prove that the provider agreements with chiropractors breached any duty to avoid unconscionable terms. [20]

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[20] In view of my finding that there is inadequate evidence on the merits as to the state law claims, it is not necessary that I resolve the defenses that these claims are barred by the applicable statutes of limitations or preempted by ERISA.

IV

For the foregoing reasons, I will grant the defendants' Motion for Summary Judgment and enter final judgment on their behalf. A separate judgment consistent with this opinion is being entered herewith.

DATED: April 25, 2003

/s/ James P. Jones
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

AMERICAN CHIROPRACTIC ASSOCIATION, ET AL.,

Plaintiffs,

v.

TRIGON HEALTHCARE, INC., ET AL.,

Defendants.

Case No. 1:00CV00113

JUDGMENT

[ENTERED: APRIL 25, 2003]

By: James P. Jones
United States District Judge

For the reasons stated in the opinion accompanying this final judgment, it is **ADJUDGED AND ORDERED** that the Motion for Summary Judgment by the defendants [Doc. No. 103] is granted and final judgment on the merits is entered in favor of the defendants.

The clerk is directed to close the case.

ENTER: April 25, 2003

/s/ James P. Jones
United States District Judge

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

FILED JUNE 2, 2004

[ENTERED: JUNE 2, 2004]

No. 03-1675
CA-00-113-1

AMERICAN CHIROPRACTIC ASSOCIATION, INCORPORATED, a non-profit corporation; VIRGINIA CHIROPRACTIC ASSOCIATION, INCORPORATED; GEORGE W. CHIRIKINIAN, D.C.; DOUGLAS M. COX, D.C.; WILLIAM R. THEISIER, D.C.; JOHN C. WILLIS, D.C.; JERRY R. WILLIS, D.C.; SARAH ELIZABETH ALLEN; LANA KAY BALL; MARGARET BYRNE; ROGER DALTON; MARY SUE DEAN; HARVIE LEE FRENCH, JR.; PATRICIA HERMAN; CINDY LINKENHOKER; SANDRA PHILLIPPI; DARLENE REQUIZO; DAVID RUSOTTO; GLORIA JEAN SMITH; LYNN D. WAGNER; ANDREA WALLACE; PATRICIA WHITTINGTON; BENIS D. WOOD; RICHARD D. WORLEY; DALE DUKE YONTZ; DOUGLAS STINE; WENDY HOLDEN WILLIS; STEVEN W. YATES; KEVIN J. WESTBY; GREGORY WALTER; JEFFERSON K. TEASS

Plaintiffs – Appellants

v.

TRIGON HEALTHCARE, INCORPORATED; TRIGON INSURANCE COMPANY; TRIGON ADMINISTRATORS; MID-SOUTH INSURANCE COMPANY; TRIGON HEALTH AND LIFE INSURANCE COMPANY

Defendants – Appellees

And

BLUE CROSS AND BLUE SHIELD ASSOCIATION

Defendant

On petition for Rehearing and Rehearing En Banc

Appellants' petition for rehearing and rehearing en banc was submitted to this Court. As no member of this Court or the panel requested a poll on the petition for rehearing en banc, and

As the panel considered the petition for rehearing and is of the opinion that it should be denied,

IT IS ORDERED that the petition for rehearing and rehearing en banc is denied.

Entered for a panel comprised of Judge Williams, Judge Michael, and Judge Quarles.

For the Court,

/s/ Patricia S. Connor
CLERK

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

American Chiropractic Association, Inc. a non-profit corporation, Virginia Chiropractic Association, Inc., Douglas F. Ambrose D.C., George W. Chirkinian D.C., Douglas M. Cox D.C., George B. McClelland D.C., James M. Porter D.C., Larry L. Stine D.C., William R. Thesier D.C., Kevin J. Westby D.C., John C. Willis D.C., Jerry R. Willis D.C., Wendy Holden Willis D.C., Steven W. Yates D.C., Sarah Elizabeth Allen, Lana Kay Ball, Margaret Byrne, Roger Dalton, Mary Sue Dean, Harvie Lee French, Jr., Patricia Herman, Cindy Linkenhoker, Sandra Phillippi, Darlene Requizo, David Russotto, Gloria Jean Smith, Lynn D. Wagner, Andrea Wallace, Patricia Whittington, Richard D. Worley, and Dale Duke Yontz,	)	CASE NO. 1:00 CV 00113
Plaintiffs,	)	Judge James P. Jones
v.	)	Trial by Jury Demanded
Trigon Healthcare, Inc., Trigon Insurance Co., Trigon Administrators, Inc., Mid-South Insurance Company, and Trigon Health and Life Insurance Company,	)	
Defendants.	)	

THIRD AMENDED COMPLAINT

Preamble

1. This Complaint alleges that the defendants have, individually and acting in concert, wrongfully harmed the plaintiffs by: an unlawful anticompetitive combination and conspiracy among Trigon companies, medical doctors, and Blue Cross and Blue Shield Association that violates the antitrust laws of the United States; by a pattern of racketeering activity by Trigon companies that includes extortion, mail fraud, wire fraud, and securities fraud and that violates the Racketeer Influenced and Corrupt Organizations Act ("RICO"); by unlawfully discriminating against chiropractic including increasing the cost to persons covered by Trigon healthcare plans of chiropractic care as compared to care by a medical doctor and paying discriminatory and inadequate compensation to doctors of chiropractic for chiropractic treatment; by conspiring to injure the practices of doctors of chiropractic by a common law conspiracy and in violation of Virginia law, Va. Ann. Code §§182-499 and 500; and by breaching obligations implied in the law of Virginia to reasonably compensate doctors of chiropractic for treatment of persons covered by Trigon healthcare plans. Plaintiffs allege upon knowledge as to themselves and their own acts and upon information and belief as to other matters based on, observations, experience, and investigation by themselves, their agents, and attorneys.

Introduction

2. The plaintiffs, the American Chiropractic Association, Inc. ("ACA") and Virginia Chiropractic Association ("VCA") bring this action on behalf of their members, doctors of chiropractic, and their patients. The plaintiff individual doctors of chiropractic bring this action on behalf of themselves and their patients. Plaintiffs ACA, VCA, and doctors of chiropractic seek to recover damages, enhanced damages, punitive damages, costs including

attorneys' fees, and equitable relief precluding defendants from engaging in wrongful acts that deny access to treatment by a licensed doctor of chiropractic to persons covered by healthcare plans sold and/or administered by Trigon Healthcare, Inc. and its subsidiaries (collectively "Trigon") and/or impede and discourage those persons from seeking treatment by doctors of chiropractic. Plaintiffs ACA, VCA, and the individual doctors of chiropractic seek reasonable compensation for services rendered by doctors of chiropractic to persons covered by healthcare plans sold and/or administered by Trigon ("Trigon healthcare plans") and for which doctors of chiropractic have received no compensation or otherwise unconscionably inadequate compensation. Plaintiff individuals who are patients of doctors of chiropractic and who are or have been covered by Trigon healthcare plans seek compensation for costs of care by a doctor of chiropractic that have not been covered by healthcare plans administered by Trigon and damages and enhanced damages for being denied care by a doctor of chiropractic by Trigon's anti-chiropractic policies and practices.

3. Over the years anti-chiropractic bias has existed in insurance companies and other organizations providing prepaid healthcare in spite of the recognition and licensing of chiropractic in all fifty states, in spite of laws passed by States prohibiting discrimination against doctors of chiropractic, and in spite of laws passed by Congress to insure access to chiropractic care by patients enrolled in government sponsored, managed healthcare programs. Certain Blue Shield healthcare plans have, in the past, been shown to exclude coverage of chiropractic services even when state law required coverage of chiropractic treatment.

4. The actions of defendants complained of here, and the bias demonstrated by defendants, is, on information and belief and historical fact, a result of medical doctors' strong

influence on and dominating presence within Trigon and a result of defendants' desire to control and reduce access to chiropractic healthcare by persons covered by Trigon healthcare plans. Upon information and belief, defendants, acting individually and in concert, have entered into a scheme to render chiropractic a secondary and marginal treatment to which access by persons covered by Trigon healthcare plans is severely restricted or eliminated altogether.

Parties

5. Plaintiff, ACA is a non-profit corporation organized under the laws of the State of Delaware. ACA's membership includes doctors of chiropractic who provide chiropractic treatment to patients throughout the Commonwealth of Virginia. ACA's address is 1701 Clarendon Blvd., Arlington, Virginia 22209.

6. Plaintiff, VCA is a non-profit professional association organized under the laws of the Commonwealth of Virginia. VCA's membership includes doctors of chiropractic who provide chiropractic treatment to patients throughout the Commonwealth of Virginia. VCA's address is 1909 Huguenot Rd., Suite 103, Richmond, Virginia 23235 (mailing address: PO Box 35231, Richmond, Virginia 23235).

7. Plaintiff George W. Chirkinian D.C. is a chiropractor who is licensed to practice in the Commonwealth of Virginia. Dr. Chirkinian's office is in Richmond, Virginia.

8. Plaintiff Douglas M. Cox D.C. is a chiropractor who is licensed to practice in the Commonwealth of Virginia. Dr. Cox's office is in Charlottesville, Virginia.

9. Plaintiff William R. Thesier D.C. is a chiropractor who is licensed to practice in the Commonwealth of Virginia. Dr. Thesier's office is in Virginia Beach, Virginia.

10. Plaintiff John C. Willis D.C. is a chiropractor who is licensed to practice in the Commonwealth of Virginia. Dr. Willis' office is in Richlands, Virginia.

11. Plaintiff Jerry R. Willis D.C. is a chiropractor who is licensed to practice in the Commonwealth of Virginia. Dr. Willis' office is in Wytheville, Virginia.

11.1 Plaintiff Douglas F. Ambrose is a chiropractor who is licensed to practice in the Commonwealth of Virginia. Dr. Ambrose has provided chiropractic treatment to patients who are insured by Trigon pursuant to an agreement with Trigon since 1998. Dr. Ambrose's office is in Richmond, Virginia.

11.2 Plaintiff George B. McClelland is a chiropractor who is licensed to practice in the Commonwealth of Virginia. Dr. McClelland has provided chiropractic treatment to patients who are insured by Trigon pursuant to an agreement with Trigon since prior to 1996. Dr. McClelland's office is in Christiansburg, Virginia.

11.3 Plaintiff James M. Porter is a chiropractor who is licensed to practice in the Commonwealth of Virginia. Dr. Porter has provided chiropractic treatment to patients who are insured by Trigon pursuant to an agreement with Trigon since 2000. Dr. Porter's office is in Wytheville, Virginia.

11.4 Plaintiff Larry L. Stine is a chiropractor who is licensed to practice in the Commonwealth of Virginia. Dr. Stine has provided chiropractic treatment to patients who are insured by Trigon pursuant to an agreement with Trigon

since prior to 1996. Dr. Stine's office is in Fredericksburg, Virginia.

11.5 Plaintiff Wendy Holden Willis is a chiropractor who is licensed to practice in the Commonwealth of Virginia. Dr. Willis has provided chiropractic treatment to patients who are insured by Trigon pursuant to an agreement with Trigon since prior to 1996. Dr. Willis' office is in Wytheville, Virginia.

11.6 Plaintiff Steven W. Yates is a chiropractor who is licensed to practice in the Commonwealth of Virginia. Dr. Yates has provided chiropractic treatment to patients who are insured by Trigon pursuant to an agreement with Trigon during the relevant period for this lawsuit. Dr. Yates's office is in Gloucester Point, Virginia.

11.7 Plaintiff Kevin J. Westby is a chiropractor who is licensed to practice in the Commonwealth of Virginia. Dr. Westby has provided chiropractic treatment to patients who are insured by Trigon pursuant to an agreement with Trigon since prior to 1996. Dr. Westby's office is in Hampton, Virginia.

12. Sarah Elizabeth Allen is a resident of Richmond, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

13. Lana Kay Ball is a resident of Cedar Bluff, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

14. Margaret Byrne is a resident of Palmyra, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

15. Roger Dalton is a resident of Rural Retreat, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

16. Mary Sue Dean is a resident of Cedar Bluff, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

17. Harvie Lee French, Jr. is a resident of Bland, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

18. Patricia Herman is a resident of Midlothian, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

19. Cindy Linkenhoker is a resident of Suffolk, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

20. Sandra Phillippi is a resident of Wytheville, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

21. Darlene Requizo is a resident of Chesapeake, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

22. David Russotto is a resident of Virginia Beach, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

23. Gloria Jean Smith is a resident of Cedar Bluff, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

24. Lynn D. Wagner is a resident of Midlothian, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

25. Andrea Wallace is a resident of Richlands, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

26. Patricia Whittington is a resident of Richlands, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

27. No averments.

28. Richard D. Worley is a resident of Bluefield, West Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

29. Dale Duke Yontz is a resident of Wytheville, Virginia who is a patient of a doctor of chiropractic and who is covered by a healthcare plan that is administered by Trigon.

30. Defendant Trigon Healthcare, Inc. is a corporation of the Commonwealth of Virginia. Trigon Healthcare, Inc.'s principal place of business is in Richmond, Virginia.

31. Defendant Trigon Insurance Company is a corporation of the Commonwealth of Virginia. Defendant Trigon Insurance Company does business as "Trigon Blue Cross Blue Shield." Defendant Trigon Insurance Company was formerly known as "Blue Cross and Blue Shield of Virginia." Defendant Trigon Insurance Company is wholly owned by Trigon Healthcare, Inc.

32. Defendant Trigon Administrators, Inc. is a corporation of the Commonwealth of Virginia. Defendant Trigon Administrators, Inc. is wholly owned by Trigon Healthcare, Inc.

33. Defendant Mid-South Insurance Company is a corporation of the State of North Carolina. Defendant Mid-South Insurance Company has its principal place of business in Richmond, Virginia. Defendant Mid-South Insurance Company is wholly owned by Trigon Healthcare, Inc.

34. Defendant Health and Life Insurance Company is a corporation of the Commonwealth of Virginia. Defendant Health and Life Insurance Company is wholly owned by Trigon Healthcare, Inc.

Jurisdiction and Venue

35. This Court has jurisdiction over this action pursuant to 15 U.S.C. §§ 15 and 26, 18 U.S.C. §1964, and 28 U.S.C. §§ 1331, 1337, and 1367.

36. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22, 18 U.S.C. §1965, 28 U.S.C. § 1391(b).

Backgound

37. Blue Cross and Blue Shield Association is a corporation of the State of Illinois. Blue Cross and Blue Shield Association's principal place of business is in Chicago, Illinois.

Chiropractic Healthcare

38. Chiropractic is a licensed healthcare profession in all fifty states and the District of Columbia. Chiropractic healthcare treatment is being sought by more and more people. It has been estimated that some 25 million patients will seek treatment from a doctor of chiropractic this year.

39. Chiropractic is concerned largely with the nerves, muscles, and skeleton, the neuromusculoskeletal system. Chiropractic seeks to reduce or eliminate pain and other symptoms by manual positioning of bones to correct abnormalities. The large majority of the practice of chiropractic is adjustment of the spine to treat abnormalities in the position of the spine, referred to as subluxations, which cause pain and other symptoms.

40. The chiropractic term "subluxation" denotes both a science and a philosophy of diagnosis and treatment:

> A spinal subluxation may be defined as an alteration of the normal statics and dynamics of the anatomical or physiological relationships of the spinal vertebrae and its resulting biomechanical and/or neurophysiological effects. These effects may be local, that is at the site of the subluxation and/or distal to the subluxation causing dysfunction to other tissues, organs and

systems, directly or indirectly affected by the subluxation. N.B. See subluxation p. 275.

Chiropractor's Manual, Laurent Boisvert, 1993, p. 91.

41. Medical physicians, osteopathic physicians and physical therapists are not qualified by education and training to diagnose spinal subluxations or to perform manual manipulation of the spine to correct a subluxation. To a medical doctor, a spinal "subluxation" connotes a complete dislocation of the spine that is untreatable by manual manipulation.

42. Chiropractic has been regulated by the Commonwealth of Virginia since 1920. Licensure of chiropractic is provided for by title 54.1 of the Code of Virginia, chapter 29, article 3.

43. Chiropractic, as defined by Title 54.1 of the Code of Virginia, "means the adjustment of the twenty-four moveable vertebrae of the spinal column, and assisting nature for the purpose of normalizing the transmission of nerve energy, but does not include the use of surgery, obstetrics, osteopathy or the administration or prescribing of any drugs or medicines." Va. Ann. Code §54.1-2900.

44. The Commonwealth of Virginia requires that health insurance coverage be provided to state employees and retired state employees that includes coverage of chiropractic treatment. Va. Ann. Code §2.1-20.1 .A.1.

45. The Commonwealth of Virginia requires that insurance policies covering liability arising from operation of an automobile cover chiropractic treatment. Va. Ann. Code §38.2-2201.1.

46. The Commonwealth of Virginia prohibits insurers from refusing reimbursement for a covered service because the service was provided by a licensed chiropractor. Va. Ann. Code §§38.2-2203, 38.2-3408, 38.2-4221, and 38.2-4312(E).

47. The number of doctors of chiropractic licensed by the Commonwealth of Virginia has grown from 493 in 1987 to 1,268 in 1996. There are now more than 1500 doctors of chiropractic licensed by the Commonwealth of Virginia.

Unlawful Discrimination Against Chiropractic by Medical Doctors

48. Chiropractors have long suffered from illegal, anti-competitive prejudice at the hands of the medical community. In 1963, the American Medical Association ("AMA") established a "Committee on Quackery" which considered "its prime mission to be, first, the containment of chiropractic and ultimately, the elimination of chiropractic."

49. The United States District Court for the Northern District of Illinois found that the AMA instituted an unlawful boycott of chiropractic intending to prevent all medical physicians in the United States from referring patients to chiropractors and from accepting referrals of patients from chiropractors, to prevent chiropractors from obtaining access to hospital diagnostic services and membership on hospital medical staffs, to prevent medical physicians from teaching at chiropractic colleges or engaging in any joint research, and to prevent any cooperation whatsoever between the two professional groups in the delivery of healthcare services.

50. In 1988, a United States District Court, in an antitrust action brought by a group of chiropractors, found that the AMA, by far the largest and most powerful

association of medical doctors, organized and led a nationwide, illegal conspiracy to "contain and eliminate" the profession of chiropractic in the United States. Wilk v. American Medical Ass'n., 671 F.Supp. 1465, 1471 (N.D. Ill. 1987). The conspiracy included, *inter alia,* an effort to ban all voluntary professional association between medical doctors, medical institutions, insurance programs, etc., and doctors of chiropractic. Affirming that decision, the United States Court of Appeals for the Seventh Circuit noted: "Indeed, the [district] court found that the AMA intended to 'destroy a competitor,' namely chiropractors." Wilk v. AMA, 895 F.2d 352, 361 (7th Cir. 1990), *cert. den.* The Seventh Circuit approved the equitable relief granted by the district court: "The district court's form of injunction and method of ensuring its publication (and thus its efficacy) was a reasonable attempt at eliminating the consequences of the AMA's lengthy, systematic, successful, and unlawful boycott." Id. at 371.

51. Anti-chiropractic bias in the world of health care, such as that which was proven to have been embraced by the AMA, its members, and its related medical doctor and health care organizations, has existed throughout the second half of the twentieth century. That bias survives today in spite of the fact that chiropractic care has been shown to be as effective, or more effective, than "traditional" medicine for certain common painful and debilitating ailments. Chiropractic can now be called a secondary, alternative, or nontraditional treatment based only on suppression of chiropractic and the continuing effects of past open and unlawful attempts of the AMA and others to suppress and destroy chiropractic.

Discrimination Against Chiropractic by Providers of Health Insurance

52. Recognizing that insurance coverage of healthcare expenses is a powerful tool that could direct patients to providers whose services were covered by healthcare insurance, the AMA sought to achieve its goal of containing and eliminating chiropractic by preventing private health insurance from covering treatment by doctors of chiropractic.

53. In 1973 the AMA worked with medical doctor dominated insurance companies to prevent any insurance payments for chiropractic services. For example, AMA staff met with Blue Shield to prevent insurance payments for chiropractic services:

> CHIROPRACTIC COVERAGE UNDER BLUE SHIELD –
>
> > [AMA] Staff will continue to maintain liaison with the National Association of Blue Shield Plans in regard to chiropractic attempts to gain coverage under Blue Shield. (NOTE: A productive meeting was held with representatives of Blue Shield on this point. They are actively considering various methods of excluding doctors of chiropractic from Blue Shield coverage.)

(Exhibit A to the originally-filed complaint at II. d, emphasis added.); and

> > 1. We [Blue Shield] have filed and may use in 5 states an exclusion deleting manipulative services and subluxations for the purpose of removing nerve interference. Basically, the

> exclusion extends to services of a chiropractor by definition.

(Exhibit B to the originally-filed complaint at B.1, emphasis added.); and

> Resistance to chiropractic payment may be indicated by the fact that fewer [Blue Shield]Plans make payment than the laws require.

(Exhibit C to the originally-filed complaint at p. 2).

54. Health insurance plans have continued to discriminate against chiropractic by imposing coverage limits based on treatments provided by chiropractors rather than based on coverage of treatment of a patient's condition, even where such discrimination is specifically illegal. In one case, a maximum annual benefit of $500.00 for "spinal manipulative therapy and any physical therapy type modalities rendered in connection therewith by an osteopathic physician, chiropractor or medical doctor" was held to be void under a state's statute requiring reimbursement for covered services provided by a doctor of chiropractic and voiding any terminology deemed discriminatory against chiropractic. Nosser v. Health Fund Trust Fund Bd., 666 So.2d 1272 (La.Ct. App. 1996). Even though the limitation literally applied to services provided by other licensed providers, the court recognized that in substance and effect, that limitation discriminates against chiropractic. *Id.* at 1276 - 77.

55. Trigon's heritage includes predecessor Blue Shield plans that were controlled by medical doctors and that discriminated against other non-medical doctor healthcare providers, clinical psychologists. *See* Va. Academy of Clinical Psy. v. Blue Shield of Va., 624 F.2d 476, (4th Cir. 1980).

56. Trigon Insurance company's predecessor, Blue Cross and Blue Shield of Virginia, extended coverage of chiropractic to all healthcare plans in 1988 only after the Commonwealth of Virginia adopted insurance equality laws that prohibited refusal to reimburse a licensed chiropractor for providing covered services. Simultaneously with offering that coverage, Blue Cross and Blue Shield of Virginia adopted a $500.00 annual limit on reimbursement for spinal manipulation, even for plans that had previously covered chiropractic treatment without such a limit. Exhibit D to the originally-filed complaint.

Blue Cross and Blue Shield Trademarks and Service Marks Provide Significant Economic Power to Sellers of Healthcare Plans

57. Blue Cross and Blue Shield Association owns trademarks and service marks for healthcare related products and services that incorporate the terms "Blue Cross", "Blue Shield", or both ("Blue Cross/Blue Shield marks").

58. Blue Cross and Blue Shield Association, its predecessors, and licensees of Blue Cross/Blue Shield marks have, for many years, promoted insurance products and services sold under the Blue Cross/Blue Shield marks.

59. Blue Cross/Blue Shield marks are recognized by 99 percent of consumers who associate those marks with "quality, dependability, choice, and nationwide acceptance."

60. The number of people covered by Blue Cross and Blue Shield healthcare plans has increased every year for the last four years.

61. As a consequence of this wide recognition, the exclusive right to sell products and services under the Blue Cross/Blue Shield marks provides a licensee of the marks a significant competitive advantage and significant economic power.

62. Blue Cross and Blue Shield Association licenses Blue Cross/Blue Shield marks to insurance companies for exclusive use in geographic regions of the United States. Within its region of exclusivity, an insurance company that has licensed Blue Cross/Blue Shield marks faces no competition from products or services sold under the Blue Cross/Blue Shield marks.

63. The Blue Cross and Blue Shield system of healthcare plans "is coordinated by the Blue Cross and Blue Shield Association."

64. As a matter of fundamental trademark law of the United States, in coordinating the system of Blue Cross and Blue Shield healthcare plans, Blue Cross and Blue Shield Association must require that products and services offered under the Blue Cross/Blue Shield marks conform to standards that the public has come to expect of products and services sold under those marks. To assure that products and services offered by licensees under the Blue Cross/Blue Shield marks conform to those standards, Blue Cross and Blue Shield Association must act in concert with licensees of the Blue Cross/Blue Shield marks and approve of the products and services with which licensees use Blue Cross/Blue Shield marks.

65. Blue Cross and Blue Shield Association permits the Blue Cross/Blue Shield marks to be used by licensees including Trigon to sell products and services that unfairly discriminate against doctors of chiropractic and their patients. In fact, state chiropractic associations from approximately eighteen (18) different states have recently reported that the Blue Cross and Blue Shield Association licensee in each respective state has instituted some form of anti-chiropractic policy.

Count I - Combination and Conspiracy in Restraint of Interstate Commerce - Trigon Companies, Blue Cross and Blue Shield Association, and Medical Doctors

66. Plaintiffs repeat the allegations of paragraphs 1 - 65.

67. Trigon Healthcare, Inc. "is the largest managed healthcare company in Virginia." Trigon Healthcare Inc. wholly owns Trigon Insurance Co., Trigon Administrators, Inc., Trigon Health and Life Insurance Company and other corporations that sell healthcare insurance and/or administer healthcare plans.

68. Until this year, Trigon Healthcare Inc. wholly owned Mid-South Insurance Company.

69. Trigon Healthcare, Inc. and its subsidiaries paid more than $2.8 billion in 1999 to healthcare providers for medical and other benefit costs of programs that they administered.

70. Trigon Healthcare, Inc. and its subsidiaries administer healthcare plans that cover approximately 32% of the residents of Virginia, which is approximately 43% of those covered by private insurance.

71. The number of persons covered by healthcare plans administered by Trigon is growing. Enrollment in those plans in Virginia increased approximately 8 % from 1998 to 1999.

72. The number of persons covered by healthcare plans sold by Trigon increased by 14.5% from June 30, 1999 to June 30, 2000, and the number' of persons covered by preferred provider organization ("PPO") healthcare plans sold by Trigon increased 36 % from June 30, 1999 to June 30, 2000.

Trigon's Policies Concerning Healthcare Providers. Including Doctors of Chiropractic, are Determined and Administered by Medical Doctors

73. Trigon Healthcare, Inc.'s wholly owned subsidiaries adhere to and enforce policies concerning healthcare providers that are determined by Trigon Healthcare, Inc.

74. The policies of Trigon Healthcare, Inc. that relate to healthcare providers, both institutions and individual healthcare practitioners, must be approved by a committee of the board of directors of Trigon Healthcare, Inc., the Provider Policy Committee.

75. The Provider Policy Committee of the Board of Directors of Trigon Healthcare, Inc. "reviews management proposals and makes recommendations to the Board of Directors of Trigon Healthcare, Inc. with respect to Trigon's policies and procedures that have a substantial impact upon institutional and professional providers of healthcare services."

76. The Provider Policy Committee consists of six members, four of whom, including the committee chairman,

are medical doctors. Though the Provider Policy Committee is a committee of the Board of Directors of Trigon Healthcare, Inc., two of the medical doctor members of that committee are not directors of Trigon Healthcare, Inc. One of those non-director members of the Provider Policy Committee is Lawrence E. Blanchard III M.D., immediate past president of the Medical Society of Virginia.

77. Medical doctors hold other positions within Trigon Healthcare, Inc. and within its wholly owned subsidiaries that are responsible for administering and executing policies concerning healthcare providers including J. Lawrence Colley, M.D., Trigon Insurance Co.'s vice president and medical director.

Medical Doctors Compete With Chiropractors and Have A Competitor's Interest in Trigon's Policies Concerning Healthcare Providers

78. It has long been established that doctors of medicine, doctors of osteopathy, and doctors of chiropractic provide competing services - i.e., patients may substitute one provider for the other based on satisfaction, perceived wellbeing, insurance coverage, etc.

79. Chiropractors and medical doctors compete with each other in the market for healthcare services, and particularly in the submarket for treatment of neuromusculoskeletal conditions of the back.

80. Medical doctors who determine policies of Trigon Healthcare, Inc. and its subsidiaries have an interest in the market for healthcare services that derives from their profession as a medical doctor and that is distinct from and in addition to their interest as a director, officer, agent, and employee of Trigon Healthcare, Inc. and/or its subsidiaries.

Healthcare Plans Sold by Trigon Under the Blue Cross/Blue Shield Marks Conform to the Requirements of the Blue Cross and Blue Shield Association

81. Trigon has licensed from Blue Cross and Blue Shield Association the exclusive right to use the Blue Cross/Blue Shield marks within the Commonwealth of Virginia other than a small portion of the northern Virginia suburbs adjacent to Washington D.C.

82. Trigon sells healthcare plans under the Blue Cross/Blue Shield marks that conform to the requirements imposed by the Blue Cross and Blue Shield Association pursuant to the agreement between Trigon and Blue Cross and Blue Shield Association granting Trigon rights to use the Blue Cross/Blue Shield marks.

83. Blue Cross and Blue Shield Association knowingly permits Trigon Insurance, Inc. to offer healthcare plans and services under the Blue Cross/Blue Shield marks that conform to and are administered in conformance with the polices concerning healthcare providers that are determined by Trigon Healthcare, Inc.

84. Blue Cross and Blue Shield Association knowingly permits Trigon use the Blue Cross/Blue Shield marks to sell healthcare plans and services that wrongfully discriminate against doctors of chiropractic.

Onerous Conditions Required of Healthcare Providers by Trigon

85. Trigon Services, Inc., on behalf of Trigon Healthcare, Inc.'s subsidiaries Trigon Insurance, Inc., Trigon Administrators, Inc., and Trigon Health and Life Insurance Company, and Trigon Healthcare, Inc.'s formerly wholly owned subsidiary Mid-South Insurance Company, entered

into agreements with healthcare providers pursuant to which healthcare providers provide and/or have provided healthcare services to persons covered by healthcare plans sold and/or administered by those subsidiaries.

86. The agreements with Trigon Services, Inc. impose conditions and obligations on healthcare providers that govern and/or govern services provided to persons covered by healthcare plans administered by those subsidiaries and that former subsidiary of Trigon Healthcare, Inc.

87. As a condition for being a provider of healthcare services to persons covered by healthcare plans sold and/or administered by those Trigon subsidiaries, a provider must agree that Trigon will determine the amount that the provider must accept as payment in full for services provided to those persons.

88. Trigon requires doctors of chiropractic to accept an "Ancillary Professional Provider Agreement" as a condition for becoming a "network" or "participating" Trigon provider. The Ancillary Professional Provider Agreement includes the requirement that the doctor of chiropractic accept Trigon's determination of the amount that is full payment for services provided by the doctor of chiropractic to persons covered by Trigon healthcare plans.

89. Nearly 95% of the physicians in the Commonwealth of Virginia have agreed to Trigon's terms for providing healthcare services to persons covered by healthcare plans administered by Trigon.

Trigon's Unreasonable Restraint on Access to Doctors of Chiropractic

90. Trigon can discourage healthcare providers from offering services to persons covered by healthcare plans administered by Trigon by requiring that providers agree to onerous terms as a condition for being a Trigon provider.

91. Trigon can direct persons covered by healthcare plans administered by Trigon away from disfavored healthcare providers and to favored healthcare providers by setting the terms and the extent of coverage of services provided by healthcare providers.

92. Trigon has sought to discourage doctors of chiropractic from offering chiropractic treatment to persons covered by healthcare plans administered by Trigon by imposing conditions for covered chiropractic treatment that are incompatible with accepted chiropractic practice and paying unconscionably inadequate reimbursements for services.

93. Trigon directs persons covered by healthcare plans that it administers to medical doctors by coveting services of medical doctors to a greater extent than those of chiropractors. Trigon has unreasonably limited the coverage of chiropractic treatment under healthcare plans that it administers and has characterized chiropractic as an alternative or nontraditional treatment. By denigrating chiropractic treatment and by unreasonably limiting the coverage of chiropractic treatment under healthcare plans that it administers, Trigon has wrongfully interfered with the choice of persons covered by healthcare plans that Trigon administers to elect to be treated by a doctor of chiropractic.

Trigon's Unreasonable Conditions on and Unconscionable Reimbursement for Chiropractic Discourage Chiropractors from Providing Services to Persons Covered by Healthcare Plans Administered by Trigon

Refusal to Cover Services of Chiropractic Assistants

94. For well more than fifty years, doctors of chiropractic have relied on trained chiropractic assistants to aid doctors of chiropractic in treating patients. The responsibilities of chiropractic assistants are limited to providing supplemental care that does not rise to the level of the practice of chiropractic. Service of chiropractic assistants is a long established and traditional part of chiropractic treatments.

95. Though chiropractic assistants have assisted doctors of chiropractic in the Virginia for many decades, the Commonwealth of Virginia has not and does not require that a person assisting a doctor of chiropractic as a chiropractic assistant obtain professional licensure. The Commonwealth of Virginia does not now and never has issued such a license.

96. Trigon refuses to reimburse the costs of services of chiropractic assistants because chiropractic assistants do not hold, because none are available, a professional license from the Commonwealth of Virginia. Doctors of chiropractic must either provide the services normally provided by chiropractic assistants themselves and seek reimbursement where available, or provide the services of a chiropractic assistant to a person covered by a healthcare plan administered by Trigon and receive no reimbursement for those services.

97. Trigon's refusal of reimbursement for the services of chiropractic assistants because the Commonwealth of

Virginia has not recognized a need for licensure of chiropractic assistants unfairly and unconscionably discriminates against doctors of chiropractic.

Unconscionably Low (Including Nothing) Reimbursement for Covered Chiropractic Treatment

98. The Trigon Ancillary Professional Provider Agreement requires doctors of chiropractic to accept amounts determined by Trigon as full payment for their services. Trigon has acted unconscionably in exploiting this requirement to impose predatory and punitively low reimbursements for the services of doctors of chiropractic, including no reimbursement at all.

99. The American Medical Association, an organization of medical doctors, has developed and published Physician's Current Professional Terminology ("CPT") codes that have been widely recognized and adopted as a basis for identifying healthcare services. The Commonwealth of Virginia has recognized the wide acceptance of those codes in requesting reimbursement from insurance companies for a healthcare provider's services. Va. Code Ann. §38.2-322(E). Trigon requires that providers submit requests for payment using CPT codes to identify the services for which payment is requested.

100. In 1997, the AMA adopted three CPT codes associated with treatments of different numbers of regions of the spine by doctors of chiropractic. Prior to 1997, only one CPT code was associated with spinal manipulation by a doctor of chiropractic.

101. The three CPT codes assigned in 1997 to chiropractic manipulation treatments of the spine ("CMT codes") each correspond to manipulation of a number of

regions of the spine, 1-2 for the lowest code, 3-4 for the next higher code, and 5 regions for the highest code.

102. A widely recognized standard for determining the value of the treatment represented by a CPT code is Medicare's Resource Based Relative Value System ("RBRVS"). An RBRVS value is assigned to each CPT code. The RBRVS value associated with a CPT code is based on the effort, training, and instruments that are required to provide the treatment represented by the CPT code.

103. Trigon represents that the amounts that it reimburses providers for treatments are set "using Medicare's Resource Based Relative Value System methodologies".

104. The CMT code that represents treatment of a larger number of regions of the spine by a doctor of chiropractic has a larger RBRVS value than a CMT code that represents treatment of fewer regions. The RBRVS value for the CMT code for treatment of 5 regions is more than 50% greater than the RBRVS value for the CMT code for treatment of 1 - 2 regions.

105. The CMT codes and associated RBRVS values adopted in 1997 are consistent with the CPT codes representing manipulations performed by a doctor of osteopathy ("OMT codes") and corresponding RBRVS values that have existed since prior to 1997. Like the RBRVS values associated with CMT codes adopted in 1997, the RBRVS values associated with OMT codes have been larger for OMT codes that represented manipulations of a greater number of regions and have been lower for OMT codes that represented manipulations of a smaller number of regions since prior to 1997.

106. Prior to 1997, Trigon reimbursed doctors of osteopathy consistently with the RBRVS values associated with OMT codes. Trigon reimbursed a greater amount for an OMT code having a larger RBRVS value than for an OMT code having a smaller RBRVS value.

107. After the CMT codes for chiropractic treatment were adopted in 1997 and replaced the single code that had previously represented spinal manipulation by a doctor of chiropractic, Trigon adopted a policy of ignoring the differences in RBRVS values between CPT codes for manual manipulation treatment by all providers who provide manual manipulation treatments of the spine. Trigon now reimburses only the amount associated with codes for the smallest number of regions regardless of the number of regions actually treated.

108. Under Trigon's policy, a doctor of chiropractic who determines that a patient covered by a Trigon healthcare plan requires treatment of more than two regions of the spine, the number represented by the CMT code having the lowest RBRVS value, and who treats all required regions, will be reimbursed by Trigon as though only two regions had been treated. Trigon's policy requires that a doctor of chiropractic who treats 3, 4, or 5 regions of a Trigon patient's spine will have treated 1, 2, or 3 regions of the spine for no reimbursement - i.e. free.

109. Trigon's policy most severely affects doctors of chiropractic because it limits reimbursement for the most important and most sought treatment provided by doctors of chiropractic, Though this policy applies to all practitioners who provide manual manipulation forms of treatment, including doctors of chiropractic, doctors of osteopathy, and physical therapists, other healthcare providers are not affected by this policy to the extent that doctors of chiropractic are affected because manual

manipulation is only one treatment provided by those other practitioners and is of lesser importance to the entirety of the their practice.

110. Even though this limitation on reimbursement affects doctors of osteopathy to a much lesser extent than doctors of chiropractic, doctors of osteopathy complained to Trigon about this 1997 change to a policy of refusing additional reimbursement for OMT codes representing additional treatment beyond the minimum number of regions. Trigon responded that its refusal to reimburse for treatment by manual manipulation of more than the minimum number of regions was intended to limit payments to chiropractors. Trigon suggested that other CPT codes for which doctors of osteopathy were authorized to bill and that are not authorized for chiropractors could be invoked so that osteopaths could avoid being economically disadvantaged by Trigon's anti-chiropractic policies.

Progressive Cuts in Reimbursement for Chiropractic Treatment

111. In addition to imposing a low limit for reimbursement for treatments primarily provided by doctors of chiropractic and refusing to reimburse doctors of chiropractic for treatment of a number of regions of the spine that is greater than the number covered by the CMT code having the lowest RBRVS value, Trigon has progressively diminished the amount that is reimbursed for services by doctors of chiropractic.

112. Trigon has, over a period of years, progressively reduced payments for services provided by chiropractors by these policies and now pays for the services of doctors of chiropractic at a rate that is approximately 40% less than the rate at which services of medical doctors are compensated.

113. By reducing compensation paid to doctors of chiropractic, even to the point of reimbursing nothing at all for treatment of more regions of the spine than are covered by the CMT code having the lowest RBRVS value, Trigon has and is excluding doctors of chiropractic from providing services under a Trigon provider agreement. By making its conditions difficult or economically impossible for doctors of chiropractic to accept, Trigon is forcing doctors of chiropractic to reject Trigon's agreements, and thereby become a provider whose services Trigon tells its covered persons will cost them the most. Doctors of chiropractic are thus left with a Hobson's choice -- dictated by an unconscionable illegal tactic of Trigon and its medical physician co-conspirators -- between exclusion from Trigon networks or accepting unconscionably and unlawfully inadequate compensation for treating persons covered by Trigon healthcare plans.

Trigon Discourages Persons Covered by Trigon Healthcare Plans from Seeking Chiropractic Treatment

114. Healthcare plans administered by Trigon reimburse different amounts for services provided by different healthcare providers. This policy allows Trigon to direct and/or encourage persons covered by those healthcare plans to seek treatment from healthcare providers favored by Trigon and to discourage those persons from seeking treatment by healthcare providers that are disfavored by Trigon.

Trigon's Networks of Providers

115. Trigon encourages persons covered by healthcare plans administered by Trigon to seek treatment from providers who have agreed that Trigon may unilaterally determine the amount the provider will receive for services provided to those persons.

116. Trigon covers the largest portion of charges for a provider's services when services are provided by members of a "network" of healthcare providers. Membership in the network is controlled by Trigon. Trigon covers a significantly lesser portion of the charges for services provided by a provider who is not a member of the network but who has agreed that Trigon may determine the provider's fees for services. Trigon thereby penalizes covered persons who seek treatment from a provider who Trigon has not included in the network for the covered person's healthcare plan.

117. Trigon tells persons covered by Trigon's healthcare plans that they will be additionally penalized if they seek treatment from a provider who has not agreed that Trigon may set the amount that a provider must accept as full compensation for the provider's services. Trigon reimburses the same amount for treatment by a provider who has not agreed that Trigon may determine the provider's fees that it reimburses for treatment by a provider who has agreed that Trigon will determine the provider's fees but who is not a member of the covered person's provider network. However, Trigon informs covered persons that the covered person will be obligated to pay more to providers who have not agreed that Trigon may determine their fees than they would be obligated to pay a provider who has agreed that Trigon may determine provider's services.

Trigon's Cap on Reimbursement for Chiropractic Treatment

118. Trigon has imposed limitations and conditions on reimbursement for services rendered by doctors of chiropractic that discourage those covered by healthcare plans administered by Trigon from seeking chiropractic treatment.

119. Trigon has imposed a maximum annual payment of $500.00 per year for "spinal manipulations and other manual medical interventions." This cap applies to charges for chiropractic treatment and limits the amount of chiropractic care that a patient can receive before the patient is solely responsible for paying for chiropractic treatment.

120. No other healthcare providers limit their practice to noninvasive manual adjustment of the neuromusculoskeletal system to the extent that doctors of chiropractic focus treatment on manual adjustment.

121. This $500.00 limitation on coverage for a treatment primarily rendered by doctors of chiropractic clearly directs patients suffering low back pain and other conditions which are regularly and successfully treated by doctors of chiropractic to seek treatments that are not subject to severe coverage limitations, principally treatments offered by medical doctors. This cap on coverage of chiropractic treatment penalizes patients who seek chiropractic treatment rather than treatment offered by a medical doctor. One court has held that such limitations are clearly discriminatory and directed to excluding doctors of chiropractic. Nosser v. Health Fund Trust Fund Bd., 666 So.2d 1272 (La.Ct. App. 1996).

Trigon Offers Additional Coverage of Chiropractic as a Treatment that is Excluded from the Scope of Primary Care

122. Trigon offers chiropractic treatment to those covered by Trigon healthcare plans characterizing doctors of chiropractic as "alternative medicine practitioners" Trigon offers this access to chiropractic treatment "[a]s a service, not a covered benefit." This program that Trigon offers requires that persons seeking chiropractic treatment to pay 75% of the charge for treatment.

123. The effect of this program and Trigon's characterization of chiropractic services offered by this program is to portray chiropractic treatment as not "traditional medicine," and a costly additional treatment that is outside the scope of healthcare services that are covered by Trigon healthcare plans.

Combination and Conspiracy in Restraint of Trade

124. By limiting the coverage of chiropractic treatment to a cost that is less than the covered cost of treatments by a medical doctor, and seeking to exclude chiropractors from its networks of providers by refusing to pay for recognized and accepted chiropractic services and by paying unreasonably and unconscionably inadequate reimbursement for those chiropractic treatments that are covered, Trigon has unreasonably restricted access to doctors of chiropractic by those covered by Trigon healthcare plans.

125. Trigon's acts and policies discriminating against doctors of chiropractic, particularly in view of the number of persons covered by Trigon healthcare plans and the number of doctors of chiropractic wrongfully injured by Trigon's discriminatory policies and acts, substantially and adversely affect interstate commerce.

126. All acts of Trigon restraining access to doctors of chiropractic by persons covered by Trigon healthcare plans are or were approved by, encouraged by, and/or suggested by competing medical doctors who advise Trigon, including those medical doctors holding positions on the Provider Policy Committee of the Board of Directors of Trigon Healthcare, Inc.

127. These medical doctors have conspired with Trigon to restrict access to doctors of chiropractic by persons

covered by Trigon healthcare plans to further the interests of medical doctors with whom doctors of chiropractic compete in treating neuromusculoskeletal abnormalities of the spine.

128. All acts of Trigon restraining access to doctors of chiropractic by persons covered by Trigon healthcare plans were approved by and aided by Blue Cross and Blue Shield Association including by allowing economically powerful Blue Cross/Blue Shield marks to be used to increase the enrollment in Trigon healthcare plans that discriminate against and restrict access to doctors of chiropractic.

129. The anti-chiropractic policies that Trigon has adopted and enforced have harmed competition by restricting the access of a large percentage of the population of Virginia to the entire licensed healthcare profession of chiropractic.

130. Trigon's anti-chiropractic policies have caused persons covered by Trigon healthcare plans who desired and/or needed chiropractic care, to either fail to visit a chiropractor or to fail to visit a chiropractor with the regularity required for adequate care. Trigons's anti-chiropractic policies have harmed those persons.

131. Trigon's anti-chiropractic policies have restricted access to doctors of chiropractic of persons who would have sought treatment from a doctor of chiropractic but for Trigon's policies. Trigon's anti-chiropractic policies have required chiropractors to accept unconscionably inadequate reimbursement for treating Trigon covered patients including no compensation at all. Therefore, chiropractors have suffered harm from lost opportunities and services rendered without fair and adequate compensation as a result of Trigon's anti-chiropractic policies.

132. The anti-chiropractic policies adopted and enforced by Trigon and its competitive medical physicians have created an illegal boycott of chiropractic and are a concerted refusal to deal with the chiropractic profession.

133. Trigon, medical doctors, and Blue Cross and Blue Shield Association have engaged in an unlawful combination and conspiracy in restraint of trade in violation of 15 U.S.C. § 1.

Count II - Attempt to Monopolize

134. Plaintiffs repeat the allegations of paragraphs 1 - 65, 67 - 133.

135. The acts of Trigon, Blue Cross and Blue Shield Association, and medical doctors are attempts to monopolize in furtherance of a conspiracy to monopolize the submarket for treatment of neuromusculoskeletal conditions of the back of the market for healthcare services in violation of 15 U.S.C. § 2.

Violation of the Racketeer Influenced and Corrupt Organizations Act

136. Plaintiffs repeat the allegations of paragraphs 1 - 65, 67 - 133.

137. Plaintiffs are "persons" within the meaning of 18 U.S.C. §§1961(3) and 1964(c).

138. Trigon Healthcare, Inc. and its subsidiaries including Trigon Insurance, Inc., Trigon Administrators, Inc., Mid-South Insurance Company, and Trigon Health and Life Insurance Company are each and are and have been collectively a "person" within the meaning of 18 U.S.C. §§1961(3) and 1962(a).

139. Trigon Healthcare, Inc. and its subsidiaries including Trigon Insurance, Inc., Trigon Administrators, Inc., Mid-South Insurance Company, and Trigon Health and Life Insurance Company are each and are and have been collectively an "enterprise" within the meaning of 18 U.S.C. §§1961(4) and 1962(a) that are and have been engaged in, or the activities of which affect and have affected, interstate commerce within the meaning of 18 U.S.C. §1962(a).

140. Trigon Healthcare, Inc. and its subsidiaries have engaged in a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5), and 1962(a).

Trigon's Extortionate Scheme - Violations of the Hobbs Act and the Virginia Extortion Statute

141. As alleged at paragraphs 70 through 72 above, Trigon healthcare plans cover a significant portion, about a third, of the population of Virginia, more than 40 % of the persons in Virginia who are covered by private health insurance. Moreover, more than 90% of the competitive medical physicians in Virginia benefit from Trigon's illegal actions.

142. Persons covered by Trigon healthcare plans first and primarily seek healthcare services that are covered to the greatest amount by their Trigon healthcare plan.

143. Trigon enjoys significant power in the market for healthcare services in Virginia, and particularly in the submarket for treatment of neuromusculoskeletal conditions of the back, based on the significant portion of the population of Virginia who look for healthcare treatment that is covered by Trigon healthcare plans and based on Trigon's fight to determine what services are covered by Trigon healthcare plans and the extent to which providers' services are covered.

144. As averred in paragraphs 85 through 89 above, for a physician's services to be covered to the greatest extent by Trigon healthcare plans, Trigon requires that a physician agree that Trigon will unilaterally determine the amount that is payment in full for the physician's services.

145. As set forth by paragraphs 98 through 113 above, Trigon has abused its rights under contracts with doctors of chiropractic by paying, since at least as early as 1998, unconscionably low reimbursements to doctors of chiropractic, including nothing at all, for services that doctors of chiropractic provide to patients covered by Trigon healthcare plans.

146. Since at least 1998, doctors of chiropractic have requested reimbursement from Trigon for treatment that was reported by CMT codes that represent treatment of more regions of the spine than are covered by the CMT code for the minimum number of regions.

147. Though Trigon has repeatedly received reimbursement requests reporting treatment of more regions of the spine than the number covered by the minimum CMT code, Trigon has reimbursed only for treatment of the regions covered by the minimum CMT code and has refused to pay any reimbursement for treatment of the regions beyond those covered by the minimum CMT code.

148. At least a significant portion of the nearly 95% of the physicians in Virginia, including doctors of chiropractic, who have agreed that Trigon will unilaterally determine the amount that the physician must accept as payment in full for the physician's services have done so based on fear of severe economic loss that they would incur if they were excluded by Trigon from the scope of the greatest coverage of Trigon healthcare plans. Exclusion from the greatest

scope of coverage would mean that the significant coercive pressure that Trigon exerts on the people covered by Trigon administered healthcare plans would direct those people away from the excluded physician and to physicians who have agreed to Trigon's terms and who are part of the covered person's Trigon network of providers.

149. At least a significant portion of the nearly 95% of the physicians in Virginia, including doctors of chiropractic, who have agreed that Trigon may unilaterally determine the amount that they must accept as full payment for their services have done so based on fear that their reputation could be perceived to be diminished as a consequence of not providing services that are within the greatest coverage of healthcare plans sold under the Blue Cross/Blue Shield marks.

150. Trigon knows that physicians who have agreed that Trigon may unilaterally determine the amount that they must accept as full payment for their services have done so based on fear of economic loss should they refuse to agree to Trigon's terms and be excluded from networks of providers for Trigon healthcare plans.

151. Trigon represents that specified costs of healthcare are covered Trigon healthcare plans. To those who are covered by a Trigon healthcare plan, the value of that plan is based on the services that are available and the extent to which those services are covered by the plan. Doctors of chiropractic directly benefit Trigon by treating persons covered by Trigon healthcare plans and provide that treatment as a service that is covered by the Trigon healthcare plan.

152. Doctors of chiropractic have treated persons covered by Trigon healthcare plans knowing that Trigon would refuse any reimbursement for some services. Doctors

of chiropractic have provided those services based on a reasonable fear of economic loss that would result from exclusion as a provider to Trigon's programs should they refuse to treat persons covered by Trigon administered healthcare plans for free.

153. Trigon knows that doctors of chiropractic have treated and continue to treat patients covered by Trigon healthcare plans knowing that Trigon will refuse to provide any reimbursement for some services because doctors of chiropractic fear the economic loss that would result from exclusion as a provider to Trigon's programs. Trigon has exploited and continues to exploit that fear to obtain treatments without any cost to Trigon for persons for whom Trigon is obligated to cover healthcare services.

154. Trigon has no legal right to refuse to pay reasonable compensation to doctors of chiropractic for services that are covered by Trigon healthcare plans and that are provided to those who are covered by Trigon healthcare plans by doctors of chiropractic.

155. Trigon has coerced doctors of chiropractic with fear of economic loss into providing services, repeatedly since at least 1998, without reasonable compensation in violation of both federal[1] and Virginia law, 18 US.C. §1951, and Virginia, Va. Ann. Code §18.2-59.

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1 *See* Brokerage Concepts, Inc. v. U.S. Healthcare, Inc., 140 F.3d 494 (3rd Cir. 1998).

156. Plaintiffs ACA's and VCA's member doctors of chiropractic have been deprived of property, and injured in their business of the practice of chiropractic by succumbing to Trigon's coercion to provide healthcare services for less than reasonable compensation, including none at all.

157. Trigon has used funds that it has wrongfully refused to pay to doctors of chiropractic as compensation for services provided to persons covered by Trigon healthcare plans to pay for services of medical doctors who compete with doctors of chiropractic in the market for healthcare services and particularly in the submarket for treatment of neuromusculoskeletal conditions of the back.

158. Trigon has used funds that it has wrongfully refused to pay to doctors of chiropractic as compensation for services provided to persons covered by Trigon healthcare plans to lower the costs of the healthcare plans that it sells and thereby enroll greater numbers of persons within healthcare plans that do not pay doctors of chiropractic reasonable compensation for healthcare services.

159. Plaintiffs ACA's and VCA's member doctors of chiropractic and plaintiff doctors of chiropractic have been deprived of property and injured in their business of the practice of chiropractic by Trigon's use of funds that it has wrongfully refused to pay to doctors of chiropractic as compensation for services provided to persons covered by Trigon healthcare plans to operate and expand its enterprise thereby increasing its ability to apply coercive pressure to patients not to seek chiropractic treatment and its ability to coerce doctors of chiropractic to accept unfair and unreasonable compensation for treating persons who are covered by Trigon healthcare plans.

Trigon's Scheme to Defraud - Mail Fraud, Wire Fraud, and Securities Fraud

160. Trigon represents that it reimburses providers of healthcare services for covered services based on RBRVS methodologies or guided by RBRVS values.

161. Trigon has made these representations in documents deposited for delivery by the United States Postal Service and in documents transmitted by wire in interstate commerce, including documents filed with the Securities and Exchange Commission.

162. Trigon intends these representations to be relied on by persons who purchase healthcare plans sold by Trigon or who engage Trigon to administer a healthcare plan according to Trigon's policies as an assurance that providers of healthcare services will be fairly compensated for providing treatment to persons who are covered by the healthcare plan.

163. Trigon intends these representations to be relied on by persons covered by Trigon healthcare plans as an assurance that providers of healthcare services under Trigon healthcare plans will be fairly compensated for providing covered treatments to those persons.

164. Trigon intends these representations to be relied on by providers of healthcare services to Trigon healthcare plans as an assurance that the providers will be fairly compensated for treatment provided to persons who are covered by Trigon healthcare plans.

165. Trigon intends these representations to be relied on by members of the public who invest in securities issued by Trigon Healthcare, Inc. that are sold to the public as an assurance that Trigon's business is based on providing

healthcare services for which providers are fairly compensated.

166. Trigon does not compensate doctors of chiropractic for chiropractic manipulation treatments based on RBRVS methodologies or guided by RBRVS values assigned to CMT codes. Trigon completely ignores the values associated with treatment of a greater number of regions of the spine than are associated with the minimum treatment CMT code. Trigon, in effect, converts to zero the values added to the RBRVS value for the minimum treatment CMT code to arrive at the higher RBRVS values of the CMT codes representing treatment of more regions of the spine.

167. Ignoring incremental RBRVS values representing the difference between treatment of the minimum number of regions of the spine and treating a greater number of regions cannot fairly or reasonably be characterized as being guided by RBRVS values or based on RBRVS methodologies. It is completely ignoring the values and methodologies.

168. Trigon's representations that it pays providers of healthcare services covered by Trigon healthcare plans based on RBRVS methodologies or guided by RBRVS values are false.

169. Trigon knows that its representations that it pays providers of healthcare services covered by Trigon healthcare plans based on RBRVS methodologies or guided by RBRVS values are false.

170. Persons covered by Trigon healthcare plans have relied on these false statements as an assurance that providers of healthcare services under Trigon healthcare plans will be fairly compensated for providing those

persons treatment that is covered by the Trigon healthcare plan.

171. Persons who have purchased healthcare plans sold by Trigon or who have engaged Trigon to administer a healthcare plan according to Trigon's policies have purchased healthcare plans or engaged Trigon to administer healthcare plans relying on those false statements as an assurance that providers of healthcare services will be fairly compensated for treating persons who are covered by the Trigon healthcare plan.

172. Providers of healthcare services to Trigon healthcare plans have relied on these false statements when entering into agreements with Trigon as an assurance that they will be fairly compensated for treatment provided to persons who are covered by Trigon healthcare plans.

173. Members of the public have invested in securities issued by Trigon Healthcare, Inc. relying on those false statements as an assurance that Trigon's business is based on fairly compensating healthcare providers for treating persons who are covered by Trigon healthcare plans.

174. Trigon knows of and has exploited that reliance on its false statements in selling healthcare plans and administration services, in encouraging physicians to agree to provide healthcare services to persons covered by Trigon's healthcare plans, in encouraging persons to seek to be covered by Trigon's healthcare plans, and in selling securities to the public.

175. Trigon has engaged in repeated and numerous acts constituting mail and wire fraud in violation of 18 U.S.C. §§ 1341 and 1343.

176. Trigon has engaged in securities fraud in violation of 15 U.S.C. §77q(a).

177. Trigon has used funds that it has received from purchasers of healthcare plans and from the investing public who relied on Trigon's false statements as an assurance that providers of healthcare services will be fairly compensated for treating persons who are covered by Trigon healthcare plans to pay for services of medical doctors who compete with doctors of chiropractic in the market for healthcare services, and particularly in the submarket for treatment of neuromusculoskeletal conditions of the back.

178. Trigon has used funds that it has received from purchasers of healthcare plans and from the investing public who relied on Trigon's false statements as an assurance that providers of healthcare services will be fairly compensated for treating persons who are covered by Trigon healthcare plans to lower the costs of the healthcare plans that it sells and thereby enroll greater numbers of persons within healthcare plans that do not pay doctors of chiropractic reasonable compensation for healthcare services.

179. Plaintiffs ACA, VCA, and member doctors of chiropractic have been injured by the increase in the number of persons covered by Trigon healthcare plans as a result of Trigon's false statements in two ways: 1)Trigon can now coerce more people to seek medical rather than chiropractic treatment; and 2) Trigon can apply even greater pressure to doctors of chiropractic to accept unfair and unreasonable compensation for treating persons who are covered by Trigon healthcare plans.

180. Trigon has used funds that it has received from purchasers of healthcare plans, from purchasers of administration services, and from the investing public, all of whom relied on Trigon's false statements as an assurance

that providers of healthcare services will be fairly compensated for treatment provided to persons who are covered by Trigon healthcare plans, to operate and expand its enterprise thereby increasing its ability to apply coercive pressure to more persons not to seek chiropractic treatment and increasing the coercive pressure that Trigon applies to doctors of chiropractic to accept unfair and unreasonable compensation for treating persons who are covered by Trigon healthcare plans.

181. Plaintiffs ACA's and VCA's member doctors of chiropractic and plaintiff doctors of chiropractic have been deprived of property and injured in their business of the practice of chiropractic by Trigon's use of funds that it has received from purchasers of healthcare plans and administration services and from the investing public, all of whom relied on Trigon's false statements as an assurance that providers of healthcare services will be fairly compensated for treatment provided to persons who are covered by Trigon healthcare plans.

182. Trigon has wrongfully deprived plaintiffs ACA's and VCA's member doctors of chiropractic and the plaintiff doctors of chiropractic of property and injured them in their business of the practice of chiropractic by depriving them of access to patients and of reasonable compensation for chiropractic treatment by a pattern of wrongful conduct including numerous and repeated violations of 18 U.S.C. §§1341, 1343.

183. Trigon has wrongfully deprived plaintiffs ACA's and VCA's member doctors of chiropractic and the plaintiff doctors of chiropractic of property, within the scope of 18 U.S.C. §1951(b)(2).

184. Trigon's repeated violations of 18 U.S.C. §§ 1341, 1343, and 1951 is a pattern of violations in support an unlawful scheme to deny doctors of chiropractic access to patients by increasing the number of persons who are covered by healthcare plans sold and/or administered by Trigon, coercing those persons not to seek chiropractic care, and requiring doctors of chiropractic to accept unreasonable and unfair conditions to be included within Trigon's healthcare plans.

185. Trigon has continued since at least 1997 and unless enjoined by this Court will continue this pattern of unlawful acts, including continuing violations of 18 U.S.C. §§ 1341, 1343, and 1951, in support of its unlawful scheme.

186. Plaintiffs ACA's and VCA's members plaintiff doctors of chiropractic have been deprived of property and injured in their business of the practice of chiropractic by Trigon's violations of 18 US.C. §1341, 1343, 1951, and 15 U.S.C. §77q(a).

187. Plaintiffs ACA, VCA, their members doctors of chiropractic, and plaintiff doctors of chiropractic have been injured in their businesses by Trigon's use of the proceeds received as a result of its pattern of violations of 18 U.S.C. §1341, 1343, 1951, and 15 U.S.C. §77q(a) within the meaning of 18 U.S.C. §1964(c).

Count IV- Tortious Interference with Business Expectancy

188. Plaintiffs repeat the allegations of paragraphs 1 - 65, 67 - 121,135 - 184.

189. Doctors of chiropractic have a reasonable expectation that some people who suffer from conditions that may be treated by chiropractic will seek treatment by a licensed doctor of chiropractic.

190. Doctors of chiropractic have a reasonable expectation that they will receive reasonable compensation for providing chiropractic treatments to patients who seek chiropractic care.

191. Doctors of chiropractic and patients of doctors of chiropractic have a reasonable expectation that the doctor/patient relationships will not be interfered with by third parties.

192. Trigon knows that some people who are covered by Trigon healthcare plans who suffer from conditions that may be treated by chiropractors would seek treatment by a doctor of chiropractic.

193. Trigon knows that doctors of chiropractic have a reasonable expectation that some people who are covered by Trigon healthcare plans and who suffer from conditions that may be treated by chiropractors, will seek treatment by a doctor of chiropractic.

194. Trigon also knows that doctors of chiropractic have formed doctor/patient relationships with certain people for whom chiropractic treatments have been effective in treating conditions and that those doctors of chiropractic have a reasonable expectation that the relationship will not be interfered with by third parties.

195. Trigon knows that doctors of chiropractic have a reasonable expectation that some people who are covered by Trigon healthcare plans and who have established a doctor/patient relationship with a doctor of chiropractic will continue to seek treatment by the doctor of chiropractic.

196. Trigon knows that doctors of chiropractic have a reasonable expectation that they will receive reasonable compensation for providing chiropractic treatments in the past, present, and future.

197. Trigon has instituted the policies, including those described by paragraphs 114 -123 above, that discourage persons covered by Trigon healthcare plans from seeking or continuing treatment by a doctor of chiropractic.

198. Trigon has also damaged the relationships of doctors of chiropractic and their patients by questioning without adequate basis the medical necessity of chiropractic treatment and informing patients that the medical necessity of chiropractic treatment was being questioned.

199. Trigon's chiropractic reimbursement policies have discouraged and/or prevented persons covered by Trigon healthcare plans who would benefit from chiropractic treatment from seeking that treatment, from obtaining the number of treatments that would be most appropriate for the patient's condition, from seeking treatment as soon as would be most appropriate for the patient's condition, and/or from seeking any additional chiropractic treatment because the five hundred dollar cap instituted by Trigon for chiropractic services had been reached.

200. Trigon's policies have interfered with the normal business and contractual relations and expectations of ACA's and VCA's member doctors of chiropractic and plaintiff doctors of chiropractic in the business and practice of providing chiropractic treatment to persons covered by Trigon healthcare plans.

201. Trigon has interfered with the reasonable contractual and business expectations of doctors of chiropractic pursuant to a conspiracy, as alleged at

paragraphs 73 - 80 and 124 - 133, with medical doctors who are in competition with doctors of chiropractic.

202. Trigon, as evidenced by its acts as alleged herein, intends to marginalize, diminish, and ultimately effectively eliminate doctors of chiropractic as healthcare providers.

203. Trigon's interference with the business expectations of doctors of chiropractic in their businesses of the practice of chiropractic has been malicious and wanton, and has caused and will cause financial and other damage to plaintiffs and other chiropractors and their patients.

Count V- Violation of Va. Ann. Code §§18.2-499

204. Plaintiffs repeat the allegations of paragraphs 1 - 65, 67 - 133, 135, 137 - 187, 189 – 203.

205. Trigon has combined with medical doctors and Blue Cross and Blue Shield Association, as set forth by paragraphs 73 - 84 above, to injure doctors of chiropractic in their businesses within Virginia.

206. Trigon and those with whom it has combined have acted willfully and maliciously to injure doctors of chiropractic in their businesses as set forth by the facts alleged above, including preventing persons from lawfully seeking chiropractic care.

207. The actions of Trigon and those who have acted in combination with Trigon are intended and designed to harm chiropractors in their trade, business, reputation, profession.

208. Trigon is liable to plaintiffs pursuant to Va. Ann. Code §18.2-500.

Count VI - Breach of Contract with Doctors of Chiropractic

209. Plaintiffs repeat the allegations of paragraphs 1 - 65, 85 - 88, 98 - 113.

210. Trigon has entered into contracts with doctors of chiropractic, including plaintiffs, as set out by paragraphs 85 - 88 providing that doctors of chiropractic will provide treatments to persons covered by Trigon healthcare plans.

211. Those contracts are governed by and construed and enforced in accordance with the laws of the Commonwealth of Virginia.

212. Those contracts obligate Trigon Insurance Co., Trigon Administrators, Inc., Mid-South Insurance Company, and Trigon Health and Life Insurance Company, subsidiaries of Trigon Healthcare, Inc., to pay or administer payment to doctors of chiropractic for services provided to persons covered by healthcare plans that were sold and/or administered by Trigon Insurance Co., and the other named subsidiaries of Trigon Healthcare, Inc.

213. Those contracts obligate the doctors of chiropractic to accept as payment in full the amount determined by Trigon Insurance Co. and other named subsidiaries of Trigon Healthcare, Inc.

214. There is an obligation in contract implied by the law of the Commonwealth of Virginia to pay reasonable compensation for services that are requested and accepted.

215. By entering into a contract to provide chiropractic services to persons covered by healthcare plans that were sold and/or administered by them and by entering into agreements with doctors of chiropractic to provide covered services to persons covered by healthcare plans sold and/or

administered by them, Trigon Insurance Co., Trigon Administrators, Inc., Mid-South Insurance Company, and Trigon Health and Life Insurance Company requested that doctors of chiropractic provide services to persons covered by their healthcare plans as requested by those persons.

216. As set out by paragraphs 98 - 113, Trigon Insurance Co. and the other named subsidiaries of Trigon Healthcare, Inc. have refused to pay any compensation to doctors of chiropractic for treatment of a number of regions of a patient's spine in excess of those covered by the CMT code for the smallest number of regions.

217. Trigon has breached the contract implied in law to pay reasonable compensation for services of doctors of chiropractic including contracts with plaintiffs ACA's and VCA's member doctors of chiropractic and plaintiff doctors of chiropractic.

Count VII --Common Law Conspiracy to Injure the Practices of Doctors of Chiropractic

218. Plaintiffs repeat the allegations of paragraphs 1 - 65, 67 - 132, 135, 137 - 187, 189-203, 205 -207, and 210-217.

219. Trigon, medical doctors, and Blue Cross and Blue Shield Association have conspired to injure the practices of doctors of chiropractic by restricting access to doctors of chiropractic of a significant portion of the population of Virginia and by wrongfully discouraging persons from seeking chiropractic treatment.

220. Trigon has committed wrongful acts in furtherance of the conspiracy to injure the practices of doctors of chiropractic that have deprived doctors of chiropractic of opportunities to treat patients whose condition was appropriate for chiropractic care and have

deprived doctors of chiropractic of reasonable compensation for chiropractic treatment provided to persons who are covered by healthcare plans that were sold and/or administered by Trigon.

221. Plaintiffs ACA's and VCA's members doctors of chiropractic and plaintiff doctors of chiropractic have been damaged by the acts of Trigon in furtherance of the conspiracy to injure the practices of doctors of chiropractic.

Violation of the Insurance Equality Laws of the Commonwealth of Virginia

222. All of the allegations above are herein realleged and incorporated herein.

223. The acts complained of and in particular capping chiropractic care benefits and paying doctors of chiropractic only 60% of the fee schedule paid to other providers for the ame or similar services violates Va. Ann. Code §§38.2-2203, 38.2-3408, 38.2-4221, and 38.2-4312(E).

224. Plaintiffs have been damaged and injured as a result of these violations by defendants and pray for damages and relief as set forth below.

Trial by Jury Demanded

225. Plaintiffs demand a trial by jury of all issues that may be so tried. WHEREFORE, plaintiffs pray this Court for the following relief

A. An Order restraining and enjoining defendants, preliminarily and permanently, from engaging in the unfair and unlawful acts and practices alleged in this complaint;

B. That defendants be ordered, jointly and severally, to pay three times actual damages pursuant to 15 U.S.C. § 15, 18 U.S.C. § 1964(c), and Va. Ann. Code § 18.2-500(a);

C. That defendants be ordered to pay plaintiffs' costs and attorneys' fees pursuant to 15 U.S.C. § 15, 18 U.S.C. §1964(c), and Va. Ann. Code §18.2-500(a);

E. For an award of punitive damages from Trigon Healthcare, Inc.; and

F. For such other and further relief as may be just and proper.

Respectfully submitted,

Date: January 8, 2002

/s/ Steven J. Hampton
George P. McAndrews
Steven J. Hampton
Patrick J. Arnold Jr.
Sharon A. Hwang
Ronald A. Dicerbo
McAndrews, Held & Malloy, Ltd.
500 West Madison Street, 34th Floor
Chicago, Illinois 60661
(312) 775-8000

Thomas R. Daly
Virginia State Bar # 19942
Odin, Feldman & Pittleman, P.C.
9302 Lee Highway Suite 1100
Fairfax, Virginia 22031
(703) 218 - 2110

William G. Shields
Virginia State Bar # 14200
William G. Shields & Associates
601 North Courthouse Rd., Suite 1
Richmond, Virginia 23236
(804) 897-4497

Attorneys for Plaintiffs, American Chiropractic Association, Virginia Chiropractic Association

CERTIFICATE OF SERVICE

I hereby certify that on the date this proof of service is signed below, I served the foregoing

PLAINTIFFS' MOTION PURSUANT TO RULE 15(a) FED. R. CIV. P. FOR LEAVE TO FILE A THIRD AMENDED COMPLAINT

in the above identified action, addressed as follows:

Howard Feller, Esq.
McGuire Woods LLP
One James Center
901 East Cary Street
Richmond, VA 23219
Facsimile: (804) 775-1061

	(BY MAIL) By placing a true copy thereof enclosed in a sealed envelope. I placed each such sealed envelope, with postage thereon fully prepaid for first-class mail.
	(BY PERSONAL SERVICE) By placing a true copy thereof enclosed in a sealed envelope. I caused each such envelope to be delivered by hand to the addressee(s) noted above.
	(BY FACSIMILE) I caused the said document to be transmitted by facsimile machine to the number indicated after the address(s) noted above.
X	(BY FEDERAL EXPRESS) By placing a true copy thereof in a sealed envelope and by causing such envelope to be placed in the Federal Express depository at Chicago, Illinois.

Richard E. Ladd, Jr. Esq.
Penn, Stuart & Eskridge
Post Office Box 2009
Bristol, VA 24203
Facsimile: (540) 466-8672

X	(BY MAIL) By placing a true copy thereof enclosed in a sealed envelope. I placed each such sealed envelope, with postage thereon fully prepaid for first-class mail.
	(BY PERSONAL SERVICE) By placing a true copy thereof enclosed in a sealed envelope. I caused each such envelope to be delivered by hand to the addressee(s) noted above.
	(BY FACSIMILE) I caused the said document to be transmitted by facsimile machine to the number indicated after the address(s) noted above.
	(BY FEDERAL EXPRESS) By placing a true copy thereof in a sealed envelope and by causing such envelope to be placed in the Federal Express depository at Chicago, Illinois.

Date: January 8, 2002 /s/ Steven J. Hampton

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
Abingdon Division

American Chiropractic Association, Inc., et al.,)
)
Plaintiffs,)
)
v.)
)
Trigon Healthcare, Inc., et al.,)
)
Defendants.)
)

Civil Action No. 1:00cv00113

ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS TRIGON HEALTHCARE, INC., TRIGON INSURANCE CO., TRIGON ADMINISTRATORS, INC., MID-SOUTH INSURANCE COMPANY AND TRIGON HEALTH AND LIFE INSURANCE COMPANY TO PLAINTIFFS' THIRD AMENDED COMPLAINT

R. Gordon Smith (VSB #5925)
Howard Feller (VSB #18248)
Bryan A. Fratkin (VSB #38933)
McGuireWoods LLP
One James Center
901 East Cary Street
Richmond, Virginia 23219
(804) 775-1000 (phone)
(804) 775-1061 (fax)

Richard E. Ladd, Jr. (VSB #30409)
Penn, Smart & Eskridge
Post Office Box 2009
Bristol, Virginia 24201
540-466-4800 (phone)
540-466-8672 (fax)

Counsel for: Trigon Healthcare, Inc.
Trigon Insurance Co.
Trigon Administrators, Inc.
Mid-South Insurance Company
Trigon Health and Life Insurance Company

Defendants Trigon Healthcare, Inc., Trigon Insurance Co., Trigon Administrators, Inc., Mid-South Insurance Company and Trigon Health and Life Insurance Company (collectively, "Trigon") state as follows for their Answer and Affirmative Defenses to Plaintiffs' Third Amended Complaint:

Answer

1. Trigon admits that Plaintiffs purport to bring this cause of action based on the allegations set forth in paragraph 1 of the Complaint, but denies the allegations in paragraph 1 of the Complaint and denies that Plaintiffs have pled or can prove any valid cause of action against Trigon on any ground whatsoever.

2. Trigon admits that Plaintiffs seek to bring this action on behalf of the parties as set forth in paragraph 2 of the Complaint, and admits that Plaintiffs seek damages as set forth in paragraph 2 of the Complaint, but denies the allegations in paragraph 2 of the Complaint, denies that Plaintiffs have standing to bring this action and denies that Plaintiffs have pled or can prove any valid cause of action against Trigon on any grounds whatsoever.

3. Trigon denies the allegations in paragraph 3 of the Complaint to the extent they relate to Trigon. Trigon is without "knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 3 of the Complaint and, therefore, these allegations are deemed denied.

4. Trigon denies the allegations in paragraph 4 of the Complaint.

5. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 of the Complaint and, therefore, these allegations are deemed denied.

6. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 6 of the Complaint and, therefore, these allegations are deemed denied.

7. Upon information and belief, Trigon admits the allegations in paragraph 7 of the Complaint.

8. Upon information and belief, Trigon admits the allegations in paragraph 8 of the Complaint.

9. Upon information and belief, Trigon admits the allegations in paragraph 9 of the Complaint.

10. Upon information and belief, Trigon admits the allegations in paragraph 10 of the Complaint.

11. Upon information and belief, Trigon admits the allegations in paragraph 11 of the Complaint.

11.1. Upon information and belief, Trigon admits the allegations in paragraph 11.1 of the Complaint.

11.2. Upon information and belief, Trigon admits the allegations in paragraph 11.2 of the Complaint that Plaintiff George B. McClelland is a chiropractor licensed to practice in Virginia, has provided chiropractic treatment to patients who are insured by Trigon and has an office in Christiansburg, Virginia. Trigon denies the remaining allegations in paragraph 11.2 of the Complaint.

11.3. Upon information and belief, Trigon admits the allegations in paragraph 11.3 of the Complaint that Plaintiff James M. Porter is a chiropractor licensed to practice in Virginia and has an office in Christiansburg, Virginia. Based on information currently available to Trigon, Trigon denies the remaining allegations in paragraph 11.3 of the Complaint.

11.4. Upon information and belief, Trigon admits the allegations in paragraph 11.4 of the Complaint.

11.5. Upon information and belief, Trigon admits the allegations in paragraph 11.5 of the Complaint that Plaintiff Wendy Holden Willis is a chiropractor licensed to practice in Virginia and has an office in Wytheville, Virginia. Based on information currently available to Trigon, Trigon denies the remaining allegations in paragraph 11.5 of the Complaint.

11.6. Upon information and belief, Trigon admits the allegations in paragraph 11.6 of the Complaint.

11.7. Upon information and belief, Trigon admits the allegations in paragraph 11.7 of the Complaint that Plaintiff Kevin J. Westby is a chiropractor licensed to practice in Virginia and has an office in Hampton, Virginia.

Based on information currently available to Trigon, Trigon denies the remaining allegations in paragraph 11.7 of the Complaint.

12. Trigon admits the allegation in paragraph 12 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 12 of the Complaint and, therefore, these allegations are deemed denied.

13. Trigon admits the allegation in paragraph 13 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 13 of the Complaint and, therefore, these allegations are deemed denied.

14. Trigon admits the allegation in paragraph 14 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 14 of the Complaint and, therefore, these allegations are deemed denied.

15. Trigon denies the allegation in paragraph 15 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 15 of the Complaint and, therefore, these allegations are deemed denied.

16. Trigon denies the allegation in paragraph 16 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 16 of the Complaint and, therefore, these allegations are deemed denied.

17. Trigon admits the allegation in paragraph 17 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 17 of the Complaint and, therefore, these allegations are deemed denied.

18. Trigon denies the allegation in paragraph 18 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 18 of the Complaint and, therefore, these allegations are deemed denied.

19. Trigon denies the allegation in paragraph 19 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 19 of the Complaint and, therefore, these allegations are deemed denied.

20. Trigon admits the allegation in paragraph 20 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 20 of the Complaint and, therefore, these allegations are deemed denied.

21. Trigon admits the allegation in paragraph 21 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 21 of the Complaint and, therefore, these allegations are deemed denied.

22. Trigon admits the allegation in paragraph 22 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 22 of the Complaint and, therefore, these allegations are deemed denied.

23. Trigon admits the allegation in paragraph 23 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 23 of the Complaint and, therefore, these allegations are deemed denied.

24. Trigon admits the allegation in paragraph 24 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 24 of the Complaint and, therefore, these allegations are deemed denied.

25. Trigon admits the allegation in paragraph 25 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 25 of the Complaint and, therefore, these allegations are deemed denied.

26. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 of the Complaint and, therefore, these allegations are deemed denied.

27. No response is required to paragraph 27 of the Complaint because it contains no averments.

28. Trigon admits the allegation in paragraph 28 of the Complaint that Plaintiff is covered by a health care plan administered by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 28 of the Complaint and, therefore, these allegations are deemed denied.

29. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 of the Complaint and, therefore, these allegations are deemed denied.

30. Trigon admits the allegations in paragraph 30 of the Complaint, except denies that its principal place of business is in Richmond, Virginia.

31. Trigon admits the allegations in paragraph 31 of the Complaint.

32. Trigon admits the allegations in paragraph 32 of the Complaint that Trigon Administrators was a Virginia corporation and was wholly-owned by Trigon Healthcare, Inc., but denies that Trigon Administrators principal place of business is in Richmond, Virginia and denies that it has any current affiliation or relationship with Trigon.

33. Trigon admits the allegations in paragraph 33 of the Complaint that Mid-South Insurance Company was incorporated in the State of North Carolina and was wholly-

owned by Trigon Healthcare, Inc., but denies that Mid-South Insurance Company had its principal place of business in Richmond, Virginia and denies that it has any current affiliation or relationship with Trigon.

34. Trigon admits the allegation in paragraph 34 of the Complaint that Trigon Health and Life Insurance Company is a Virginia Corporation but denies the remaining allegations in paragraph 34 of the Complaint.

35. Trigon admits that Plaintiffs purport to invoke the Court's jurisdiction under the statutes cited, but denies the allegations in paragraph 36 of the Complaint.

36. Trigon admits that Plaintiffs purport to establish venue under the statutes cited, but denies the allegations in paragraph 37 of the Complaint.

37. Upon information and belief, Trigon admits the allegations in paragraph 35 of the Complaint.

38. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 38 of the Complaint and, therefore, these allegations are deemed denied.

39. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 39 of the Complaint and, therefore, these allegations are deemed denied.

40. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 40 of the Complaint and, therefore, these allegations are deemed denied.

41. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41 of the Complaint and, therefore, these allegations are deemed denied.

42. As to the allegations in paragraph 42 of the Complaint, Trigon admits that Title 54.1 of the Code of Virginia, Chapter 29, Article 3, concerns the licensure of chiropractic. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 42 of the Complaint and, therefore, these allegations are deemed denied.

43. As to the allegations in paragraph 43 of the Complaint, Trigon states that Virginia Code § 54.1-2900 speaks for itself and denies the allegations to the extent they are inconsistent with the Virginia Code.

44. As to the allegations in paragraph 44 of the Complaint, Trigon states that Virginia Code § 2.1-20.1(A)(1) speaks for itself and denies the allegations to the extent they are inconsistent with the Virginia Code.

45. As to the allegations in paragraph 45 of the Complaint, Trigon states that Virginia Code § 38.2-2201.1 speaks for itself and denies the allegations to the extent they are inconsistent with the Virginia Code.

46. As to the allegations in paragraph 46 of the Complaint, Trigon states that Virginia Code §§ 38.2-2203, 38.2-3408, 38.2-4221 and 38.2-4312(E) speak for themselves and denies the allegations to the extent they are inconsistent with the Virginia Code.

47. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 47 of the Complaint and, therefore, these allegations are deemed denied.

48. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 48 of the Complaint and, therefore, these allegations are deemed denied.

49. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 49 of the Complaint and, therefore, these allegations are deemed denied.

50. As to the allegations in paragraph 50 of the Complaint, Trigon states that the courts' opinions speak for themselves and denies the allegations to the extent they are inconsistent with the courts' opinions.

51. Trigon denies the allegations in paragraph 51 of the Complaint to the extent that they relate to Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 51 of the Complaint and, therefore, these allegations are deemed denied.

52. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 52 of the Complaint and, therefore, these allegations are deemed denied.

53. As to the allegations in paragraph 53 of the Complaint, Trigon states that Exhibits A, B and C, attached to the Complaint, speak for themselves and denies these allegations to the extent they are inconsistent with these Exhibits. Trigon is without knowledge or information

sufficient to form a belief as to the truth of the remaining allegations in paragraph 53 of the Complaint and, therefore, these allegations are deemed denied.

54. Trigon denies the allegations in paragraph 54 of the Complaint to the extent that they relate to Trigon. Trigon further states that the court's opinion speaks for itself and denies these allegations to the extent they are inconsistent with the court's opinion. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 54 of the Complaint and, therefore, these allegations are deemed denied.

55. Trigon denies the allegations in paragraph 55 of the Complaint.

56. Trigon denies the allegations in paragraph 56 of the Complaint. Trigon further states that Exhibit D, attached to the Complaint, speaks for itself and denies these allegations to the extent they are inconsistent with Exhibit D.

57. Upon information and belief, Trigon admits the allegations in paragraph 57 of the Complaint.

58. Upon information and belief, Trigon admits the allegations in paragraph 58 of the Complaint.

59. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 59 of the Complaint and, therefore, these allegations are deemed denied.

60. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 60 of the Complaint and, therefore, these allegations are deemed denied.

61. Trigon denies the allegations in paragraph 61 of the Complaint.

62. Upon information and belief, Trigon admits the allegations in paragraph 62 of the Complaint.

63. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 63 of the Complaint because "system of healthcare plans" is not defined and the source of the quotation is not identified; therefore, these allegations are deemed denied.

64. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 64 of the Complaint as to whether the allegations are a matter of fundamental trademark law in the United States and, therefore, these allegations are deemed denied. Trigon denies the allegations in the second sentence of paragraph 64 of the Complaint. Trigon further states that, over time, it has entered into trademark license agreements with the Blue Cross and Blue Shield Association and acts in accordance with the terms and conditions of those agreements.

65. Trigon denies the allegations in the first sentence of paragraph 65 of the Complaint. Trigon denies the allegations in the second sentence of paragraph 65 of the Complaint that it has instituted any form of anti-chiropractic policy. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 65 of the Complaint and, therefore, these allegations are deemed denied.

66. Trigon incorporates its responses to paragraphs 1 through 65 above.

67. Trigon admits that the quoted statement in paragraph 67 of the Complaint has been made in Trigon publications but denies that it has any market power and further avers that there are larger managed health care companies which are conducting business within the Commonwealth of Virginia. Trigon further admits the allegations in paragraph 67 of the Complaint that Trigon Healthcare, Inc. wholly owns Trigon Insurance Company, Trigon Health and Life Insurance Company and other corporations that sell healthcare insurance and/or administer healthcare plans but denies that Trigon Healthcare, Inc. wholly owns Trigon Administrators.

68. Trigon admits the allegations in paragraph 68 of the Complaint that until 2000 it wholly owned Mid-South Insurance Company.

69. Trigon admits the allegations in paragraph 69 of the Complaint.

70. Trigon denies the allegations in paragraph 70 of the Complaint.

71. Trigon admits the allegations in paragraph 71 of the Complaint.

72. Trigon admits the allegations in paragraph 72 of the Complaint that the number of persons covered by PPO healthcare plans sold by Trigon increased 36% from June 30, 1999 to June 30, 2000, and denies the remaining allegation in paragraph 72 of the Complaint.

73. Trigon denies the allegations in paragraph 73 of the Complaint.

74. Trigon denies the allegations in paragraph 74 of the Complaint.

75. As to the allegations in paragraph 75 of the Complaint, Trigon admits that the Provider Policy Committee may review management proposals and may make recommendations to the Board of Directors but denies the remaining allegations in paragraph 75 of the Complaint.

76. Trigon admits the allegations in paragraph 76 of the Complaint that the Provider Policy Committee is a committee of the Board of Directors, that two of the members are not directors of Trigon and that Dr. Blanchard is a member of the PPC. Trigon denies the remaining allegations in pargraph 76 of the Complaint.

77. Trigon denies the allegations in paragraph 77 of the Complaint.

78. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 78 of the Complaint and, therefore, these allegations are deemed denied.

79. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 79 of the Complaint and, therefore, these allegations are deemed denied.

80. Trigon denies the allegations in paragraph 80 of the Complaint.

81. Trigon admits the allegations in paragraph 81 of the Complaint that it has licensed from Blue Cross and Blue Shield Association the exclusive right to use the Blue Cross/Blue Shield marks within the Commonwealth of Virginia other than a portion of Northern Virginia adjacent to Washington, D.C., but denies the remaining allegations in paragraph 81 of the Complaint.

82. Trigon admits the allegations in paragraph 82 of the Complaint that it sells healthcare plans under the Blue Cross/Blue Shield mark and that its use of the mark conforms to the license agreement between Trigon and the Blue Cross and Blue Shield Association, but denies the remaining allegations in paragraph 82 of the Complaint.

83. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 83 of the Complaint and, therefore, these allegations are deemed denied.

84. Trigon denies the allegations in paragraph 84 of the Complaint.

85. Trigon admits the allegations in paragraph 85 of the Complaint.

86. Trigon admits the allegations in paragraph 86 of the Complaint.

87. Trigon denies the allegations in paragraph 87 of the Complaint.

88. Trigon admits the allegations in paragraph 88 of the Complaint that its contracts with chiropractors are entitled Ancillary Professional Provider Agreements and that by signing the contract, chiropractors become part of Trigon's network or participating providers and denies the remaining allegations in paragraph 88 of the Complaint. Trigon further states that the Ancillary Professional Provider Agreements speak for themselves and denies these allegations to the extent they are inconsistent with the Ancillary Professional Provider Agreements.

89. Trigon admits the allegations in paragraph 89 of the Complaint that approximately 95% of physicians in the Commonwealth have entered into contracts with Trigon.

90. Trigon denies the allegations in paragraph 90 of the Complaint.

91. Trigon denies the allegations in paragraph 91 of the Complaint.

92. Trigon denies the allegations in paragraph 92 of the Complaint.

93. Trigon denies the allegations in paragraph 93 of the Complaint.

94. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 94 of the Complaint and, therefore, these allegations are deemed denied.

95. Trigon admits the allegations in paragraph 95 of the Complaint that the Commonwealth of Virginia does not require that chiropractic assistants obtain professional licensure. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining

allegations in paragraph 95 of the Complaint and, therefore, these allegations are deemed denied.

96. Trigon denies the allegations in paragraph 96 of the Complaint.

97. Trigon denies the allegations in paragraph 97 of the Complaint.

98. Trigon denies the allegations in paragraph 98 of the Complaint.

99. Trigon admits the allegations in paragraph 99 of the Complaint that it requires that providers submit requests for payment using CPT codes or alternative codes, such as HCPCS, designated by Trigon. Trigon is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 99 of the Complaint and, therefore, these allegations are deemed denied.

100. Trigon admits the allegations in paragraph 100 of the Complaint that in 1997 the AMA adopted three CPT codes associated with treatments of different numbers of regions of the spine by chiropractors but denies the remaining allegations in paragraph 100 of the Complaint.

101. Trigon admits the allegations in paragraph 101 of the Complaint that the CPT codes correspond to manipulation of a number of regions of the spine but denies the remaining allegations in paragraph 101 of the Complaint.

102. Trigon admits the allegations in paragraph 102 of the Complaint that RBRVS is one resource used in the industry for determining reimbursement levels and denies the remaining allegations in paragraph 102 of the Complaint.

103. Trigon admits the allegations in paragraph 103 of the Complaint that the amounts that it reimburses providers for treatment are set by considering, among other things, Medicare's Resource Based Relative Value System. Trigon further states that it reimburses providers based on the amounts set forth in its provider agreements and denies the remaining allegations in paragraph 103 of the Complaint.

104. Trigon admits the allegations in the first sentence of paragraph 104 of the Complaint. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of paragraph 104 of the Complaint and, therefore, these allegations are deemed denied.

105. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 105 of the Complaint and, therefore, these allegations are deemed denied.

106. Trigon denies the allegations in paragraph 106 of the Complaint.

107. Trigon denies the allegations in paragraph 107 of the Complaint.

108. Trigon denies the allegations in paragraph 108 of the Complaint.

109. Trigon denies the allegations in paragraph 109 of the Complaint.

110. Trigon denies the allegations in paragraph 110 of the Complaint.

111. Trigon denies the allegations in paragraph 111 of the Complaint.

112. Trigon denies the allegations in paragraph 112 of the Complaint.

113. Trigon denies the allegations in paragraph 113 of the Complaint.

114. Trigon denies the allegations in paragraph 114 of the Complaint.

115. Trigon denies the allegations in paragraph 115 of the Complaint.

116. Trigon denies the allegations in paragraph 116 of the Complaint.

117. Trigon denies the allegations in paragraph 117 of the Complaint.

118. Trigon denies the allegations in paragraph 118 of the Complaint.

119. Trigon admits the allegations in paragraph 119 of the Complaint that there is a $500 coverage limit for spinal manipulations and other manual medical interventions in many of its health care policies issued to employers or groups, but denies the remaining allegations in paragraph 119.

120. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 120 of the Complaint and, therefore, these allegations are deemed denied.

121. As to the allegations in paragraph 121 of the Complaint, Trigon states that the court's opinion speaks for itself and denies the allegations to the extent they are inconsistent with the court's opinion. Trigon denies the remaining allegations in paragraph 121 of the Complaint.

122. Trigon denies the allegations in paragraph 122 of the Complaint.

123. Trigon denies the allegations in paragraph 123 of the Complaint.

124. Trigon denies the allegations in paragraph 124 of the Complaint.

125. Trigon denies the allegations in paragraph 125 of the Complaint.

126. Trigon denies the allegations in paragraph 126 of the Complaint.

127. Trigon denies the allegations in paragraph 127 of the Complaint.

128. Trigon denies the allegations in paragraph 128 of the Complaint.

129. Trigon denies the allegations in paragraph 129 of the Complaint.

130. Trigon denies the allegations in paragraph 130 of the Complaint.

131. Trigon denies the allegations in paragraph 131 of the Complaint.

132. Trigon denies the allegations in paragraph 132 of the Complaint.

133. Trigon denies the allegations in paragraph 133 of the Complaint.

134. Trigon incorporates its responses to paragraphs 1 through 133 above.

135. Trigon denies the allegations in paragraph 135 of the Complaint.

136. Trigon incorporates its responses to paragraphs 1 through 135 above.

137. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 137 of the Complaint.

138. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 138 of the Complaint.

139. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 139 of the Complaint.

140. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 140 of the Complaint.

141. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 141 of the Complaint.

142. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 142 of the Complaint and, therefore, these allegations are deemed denied.

143. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 143 of the Complaint.

144. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 144 of the Complaint.

145. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 145 of the Complaint.

146. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 146 of the Complaint except to admit that some chiropractors have in the past requested additional reimbursement for treatment of three or more regions of the spine.

147. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 147 of the Complaint except to admit that some chiropractors have in the past requested additional reimbursement for treatment of three or more regions of the spine.

148. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 148 of the Complaint.

149. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 149 of the Complaint.

150. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 150 of the Complaint.

151. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 151 of the Complaint, except to admit that certain healthcare services are covered by Trigon's healthcare plans.

152. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 152 of the Complaint.

153. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 153 of the Complaint.

154. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 154 of the Complaint.

155. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 155 of the Complaint.

156. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 156 of the Complaint.

157. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 157 of the Complaint.

158. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 158 of the Complaint,

159. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 159 of the Complaint.

160. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 160 of the Complaint.

161. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 161 of the Complaint.

162. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 162 of the Complaint.

163. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 163 of the Complaint.

164. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 164 of the Complaint.

165. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 165 of the Complaint.

166. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 166 of the Complaint.

167. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 167 of the Complaint.

168. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 168 of the Complaint.

169. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 169 of the Complaint.

170. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 170 of the Complaint.

171. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 171 of the Complaint.

172. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 172 of the Complaint.

173. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 173 of the Complaint.

174. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 174 of the Complaint.

175. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 175 of the Complaint.

176. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 176 of the Complaint.

177. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 177 of the Complaint.

178. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 178 of the Complaint.

179. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 179 of the Complaint.

180. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 180 of the Complaint.

181. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 181 of the Complaint.

182. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 182 of the Complaint.

183. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 183 of the Complaint.

184. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 184 of the Complaint.

185. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 185 of the Complaint.

186. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 186 of the Complaint.

187. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the RICO Act, Trigon denies the allegations in paragraph 187 of the Complaint.

188. Trigon incorporates its responses to paragraphs 1 through 187 above.

189. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 189 of the Complaint and, therefore, these allegations are deemed denied.

190. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 190 of the Complaint and, therefore, these allegations are deemed denied.

191. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 191 of the Complaint and, therefore, these allegations are deemed denied.

192. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 192 of the Complaint and, therefore, these allegations are deemed denied.

193. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 193 of the Complaint and, therefore, these allegations are deemed denied.

194. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 194 of the Complaint and, therefore, these allegations are deemed denied.

195. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 195 of the Complaint and, therefore, these allegations are deemed denied.

196. Trigon is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 196 of the Complaint and, therefore, these allegations are deemed denied.

197. Trigon denies the allegations in paragraph 197 of the Complaint.

198. Trigon denies the allegations in paragraph 198 of the Complaint.

199. Trigon denies the allegations in paragraph 199 of the Complaint.

200. Trigon denies the allegations in paragraph 200 of the Complaint.

201. Trigon denies the allegations in paragraph 201 of the Complaint.

202. Trigon denies the allegations in paragraph 202 of the Complaint.

203. Trigon denies the allegations in paragraph 203 of the Complaint.

204. Trigon incorporates its responses to paragraphs 1 through 203 above.

205. Trigon denies the allegations in paragraph 205 of the Complaint.

206. Trigon denies the allegations in paragraph 206 of the Complaint.

207. Trigon denies the allegations in paragraph 207 of the Complaint.

208. Trigon denies the allegations in paragraph 208 of the Complaint.

209. Trigon incorporates its responses to paragraphs 1 through 208 above.

210. As to the allegations in paragraph 210 of the Complaint, Trigon states that the contracts speak for themselves and admits that it has entered into contracts with doctors of chiropractic, but denies the remaining allegations in paragraph 210 of the Complaint.

211. Trigon admits the allegations in paragraph 211 of the Complaint.

212. As to the allegations contained paragraph 212 of the Complaint, Trigon states that the contracts speak for themselves and denies the allegations to the extent they are inconsistent with the contracts.

213. Trigon denies the allegations in paragraph 213 of the Complaint except to admit that the contracts obligate the doctors of chiropractic to accept as payment in full the amounts agreed to by the doctors of chiropractic and Trigon.

214. Trigon denies the allegations in paragraph 214 of the Complaint.

215. As to the allegations contained in paragraph 215 of the Complaint, Trigon states that the contracts speak for themselves and denies the allegations to the extent they are inconsistent with the contracts. Trigon denies the remaining allegations in paragraph 215 of the Complaint.

216. Trigon denies the allegations in paragraph 216 of the Complaint.

217. Trigon denies the allegations in paragraph 217 of the Complaint.

218. Trigon incorporates its responses to paragraphs 1 through 217 above.

219. Trigon denies the allegations in paragraph 219 of the Complaint.

220. Trigon denies the allegations in paragraph 220 of the Complaint.

221. Trigon denies the allegations in paragraph 221 of the Complaint.

222. Trigon incorporates its responses to paragraphs 1 through 221 above.

223. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the insurance laws of the Commonwealth of Virginia, Trigon denies the allegations in paragraph 223 of the Complaint.

224. Trigon states that while no response should be required based on the Court's dismissal of Plaintiffs' cause of action for alleged violations of the insurance laws of the Commonwealth of Virginia, Trigon denies the allegations in paragraph 224 of the Complaint.

225. Trigon admits that Plaintiffs have demanded a trial by jury the allegations in paragraph 225 of the Complaint, but denies that there are any jury issues in this action.

226. Trigon denies that Plaintiffs are entitled to any of the relief set forth in the WHEREFORE clause, including all of the subparagraphs set forth therein, of the Complaint.

227. All allegations not specifically admitted herein are denied.

Affirmative Defenses

Without assuming the burden of proof on any defenses that would otherwise rest with Plaintiffs, and expressly denying any and all wrongdoing, Trigon alleges the following additional reasons why Plaintiffs are not entitled to pursue their claims or to recover anything from Trigon. In addition to the Affirmative Defenses set forth below, Trigon intends to rely on all other properly provable defenses and reserves the right to amend its Answer to and through the time of trial.

FIRST AFFIRMATIVE DEFENSE

As and for a first separate, distinct and affirmative defense, Trigon alleges that the Complaint fails to state a claim or claims upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

As and for a second separate, distinct and affirmative defense, Trigon alleges that this action may be barred, in whole or in part, by the applicable statutes of limitations.

THIRD AFFIRMATIVE DEFENSE

As and for a third separate, distinct and affirmative defense, Trigon alleges that this action may be barred, in whole or in part, by the doctrine of laches.

FOURTH AFFIRMATIVE DEFENSE

As and for a fourth separate, distinct and affirmative defense, Trigon alleges that this action may be barred, in whole or in part, by the doctrines of estoppel and *res judicata*.

FIFTH AFFIRMATIVE DEFENSE

As and for a fifth separate, distinct and affirmative defense, Trigon alleges that this action may be barred, in whole or in part, to the extent Plaintiffs seek improper, excessive and unreasonable multiple and punitive awards for a single wrong. Such awards would violate Trigon's fights under the United States Constitution and the Virginia Constitution, specifically the Due Process Clause of the Fifth Amendment and Fourteenth Amendments to the United States Constitution; the Sixth Amendment to the United States Constitution; the Eighth Amendment to the United States Constitution; and the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

As and for a sixth separate, distinct and affirmative defense, Trigon alleges that this action may be barred, in whole or in part, because any conduct or action of Trigon was and is reasonable and lawful based on independent, legitimate business and economic justifications.

SEVENTH AFFIRMATIVE DEFENSE

As and for a seventh separate, distinct and affirmative defense, Trigon alleges that this action may be barred because Trigon has engaged in no conduct in combination with any other persons and has always acted unilaterally and independently.

EIGHTH AFFIRMATIVE DEFENSE

As and for an eighth separate, distinct and affirmative defense, Trigon alleges that this action may be barred, in whole or in part, because Trigon has engaged in no activity or conduct that is a proximate cause of any injury alleged by Plaintiffs.

NINTH AFFIRMATIVE DEFENSE

As and for a ninth separate, distinct and affirmative defense, Trigon alleges that this action may be barred by the intracorporate immunity doctrine.

TENTH AFFIRMATIVE DEFENSE

As and for a tenth separate, distinct and affirmative defense, Trigon alleges that this action may be barred, in whole or in part, because some or all Plaintiffs' lack standing, including antitrust standing, to bring or maintain this action.

ELEVENTH AFFIRMATIVE DEFENSE

As and for an eleventh separate, distinct and affirmative defense, Trigon alleges that some of Plaintiffs claims are preempted by § 514 of the Employee Retirement Income Security Act, 29 U.S.C §§ 1001 *et seq.*

WHEREFORE, Defendants move this Court for an order dismissing Plaintiffs' action against them and awarding them costs expended herein and such other, further and additional relief as may be warranted.

Dated: January 17, 2002

Respectfully submitted,

Trigon Healthcare, Inc., Trigon Insurance Co.,
Trigon Administrators, Inc.,
Mid-South Insurance Company and
Trigon Health and Life Insurance Company

By /s/_____

R. Gordon Smith (VSB #5925)
Howard Feller (VSB #18248)
Bryan A. Fratkin (VSB #38933)
McGuireWoods LLP
One James Center
901 East Cary Street
Richmond, Virginia 23219
(804) 775-1000 (phone)
(804) 775-1061 (fax)

Richard E. Ladd, Jr. (VSB #30409)
Penn, Stuart & Eskridge
Post Office Box 2009
Bristol, Virginia 24201
540-466-4800 (phone)
540-466-8672 (fax)

Certificate of Service

I hereby certify that on this 17th day of January, 2002, a true copy of the foregoing was sent via Federal Express, to:

George P. McAndrews, Esquire
Steven J. Hampton, Esquire
Peter J. McAndrews, Esquire
McAndrews, Held & Malloy, Ltd.
500 West Madison Street, 34th Floor
Chicago, Illinois 60661
(312) 775-8000

Thomas R. Daly, Esquire
(VSB # 19942)
Odin, Feldman & Pittleman, P.C.
9302 Lee Highway, Suite 1100
Fairfax, Virginia 22031
(703) 218-2110

William G. Shields, Esquire
(VSB # 14200)
William G. Shields & Associates
601 North Courthouse Rd., Suite 1
Richmond, Virginia 23236
(804) 897-4497

Counsel for Plaintiffs

/s/_____

R-4025/1 -COR/FOER

The Appropriateness of Spinal Manipulation for Low-Back Pain

Project Overview and Literature Review

Paul G. Shekelle, Alan H. Adams, Mark R. Chassin, Eric L. Hurwitz, Reed B. Phillips, Robert H. Brook

Supported by the
Consortium for Chiropractic Research
Foundation for Chiropractic Education and Research

PREFACE

This report presents results from one part of the RAND Appropriateness of Spinal Manipulation for Low-Back-Pain Study. The study is designed to ascertain the clinical criteria *for* the appropriate use of spinal manipulation for low-back pain from chiropractors and medical specialists and then to investigate the use of chiropractic services (particularly spinal manipulation) in a random sample of practicing chiropractors. The study has four major stages:

- Stage I reviewed the medical literature to summarize knowledge about efficacy, complications, and indications for spinal manipulation for low-back pain.

- Stage II convened a panel of back-pain experts from the disciplines of orthopedics, chiropractic, osteopathy, internal medicine, family medicine, and neurology~ to discuss and rate for appropriateness a large number of

indications for spinal manipulation for low-back pain.

- Stage III will convene a second, all-chiropractic panel of experts, to discuss and rate the same indications for spinal manipulation for low-back pain.

- Stage IV will analyze the use of services in a random sample of practicing chiropractors, with an emphasis on abstraction of medical records for patients treated for low-back pain.

This report presents the results of the first stage. It describes what is known in the medical literature about the utilization, efficacy, complications, and indications for spinal manipulation for low-back pain. It should be of interest to clinicians who perform spinal manipulation, clinicians who deal with patients with back pain, and to health researchers concerned with the appropriate indications for performing medical procedures.

This research is a joint undertaking of RAND; the UCLA Division of General Internal Medicine, Department of Medicine; the Consortium for Chiropractic Research (car); the Foundation for chiropractic Education and Research (FCER); and Value Health Sciences, Inc. Support has been provided by the CCR and the FCER.

SUMMARY

This report contains a literature review of spinal manipulation for low-back pain.

Spinal manipulation is a manual procedure that involves a directed thrust to move a joint ~ the physiologic range of motion without exceeding the anatomic range of motion. Spinal manipulation has been used for centuries as a treatment for musculoskeletal complaints. In recent times, the use of spinal manipulation has been equated with the practice of chiropractic~-. , in part because of this, spinal manipulation has been labeled n "unorthodox" treatment by the medical profession. This review covers the literature from 1955 to the present on the use of spinal manipulation. It gathers data from 76 sources including 22 controlled trial of the use of spinal manipulation for low-back pain.

UTILIZATION

Based on limited data, it is estimated that about 5% of the U.S. population annually uses chiropractors. The majority of patients seek care for back pain and related complaints and are usually treated with spinal manipulation. The course of treatment generally involves multiple visits and manipulations, between 5 and 18 per episode. This care is delivered by about 45,000 chiropractors at a cost of approximately $2.4 billion annually. In one study, chiropractors delivered upwards of 90% of the manipulative therapy for which reimbursement was sought. Chiropractic patients are more likely to be white, middle-aged, and employed than the general population.

COMPLICATIONS

There is no systematic report on the frequency of complications. Collections of anecdotal reports suggest that the serious complications of spinal manipulation include death, paraplegia, and advancement of unrecognized coexisting medical disorders because of misdiagnosis. The rate of these occurrences is probably low, but the lack of data in the literature prevents firm conclusions.

EFFICACY

The literature on the efficacy of spinal manipulation is of uneven quality. While many studies are randomized controlled trials, there is a great diversity in the initial selection and evaluation of patients for study, assignment of those patients to spinal manipulation or a control treatment, the type of spinal manipulation given, the type of control treatment given, and the method of assessing a response. Given that caveat, support is consistent for the use of spinal manipulation as a treatment for patients with acute low-back pain and an absence of other signs or symptoms of lower limb nerve-root involvement. Support is less clear for other indications, with the evidence for some insufficient (acute and subacute low-back pain with sciatica, acute and subacute low-back pain with minor lower limb neurologic findings, most types of chronic back pain), while the evidence for others is conflicting (acute low-back pain with sciatica and minor lower limb neurological findings, subacute low-back pain without sciatica, and chronic low-back pain without sciatica).

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1. PROJECT OVERVIEW

The appropriateness with which health services are used has been gaining increasing attention over the last decade. As health care costs continue to climb and as evidence mounts that some medical and surgical procedures are overused, there is a growing perception that the United States is not receiving sufficient value for its expenditures

on health. The demonstration of large geographic variations in the use rate of medical care, beyond those explained by underlying differences in the populations at risk, has led some to question whether physicians agree on the type and amount of medical care that is appropriate for certain conditions. Considerable research has indicated uncertainty even among nationally recognized experts in the conditions under question. This underlying uncertainty about how to treat certain diseases may be in part responsible for overuse and for the needless expenditure and risk such inappropriate use places upon payors and patients.

Back pain occurs in up to 80% of adults at some point in their lives (Deyo, 1983) and is one of the leading causes of visits to physicians (Deyo, 1983; Deyo, 1987). Except in rare presentations, it is appropriate for most persons with back pain to undergo an initial course of conservative therapy (Deyo, 1983). These conservative measures have included oral medications, injectable drugs, counter-stimulation (such as transcutaneous electrical nerve stimulation. and physical measures (such as bedrest, corsets, exercises, and manipulation). Manipulation is among the most controversial of these measures. Although practiced for centuries, no evidence to date conclusively proves the effectiveness or lack thereof for the use of spinal manipulation to treat back pain. This, combined with the association of spinal manipulation with the practice of chiropractic, has relegated the use of spinal manipulation to the unorthodox' category of treatments among the medical (allopathic) profession.

Spinal manipulation, however, is the most commonly used conservative treatment for low back pain for which reimbursement is sought. About two-thirds of all patient visits for back pain are made to chiropractors (Murt, 1986). Most of these patients are treated with spinal manipulation. This care cost approximately $2.4 billion in

19~8 *(FACTS Bulletin),* while the total cost of direct medical care for back pain in the United States is estimated at $8 billion annually (Bonica, 1982).

For all of these reasons—the prevalence of back pain in America, its cost to society, and the uncertainty about the role spinal manipulation should play in its treatment—RAND; the UCLA Division of General Internal Medicine, Department of Medicine; the Consortium for Chiropractic Research (CCR); the Foundation for Chiropractic Education and Research FCER); and Value Health Sciences, Inc. (VHS), have undertaken an examination of the appropriate use of spinal manipulation in the treatment of low-back pain. Support has been provided by the National Institutes of Health, the CCR, and the FCER.

This project will result in a comprehensive set of indications for performing spinal manipulation for persons with low-back pain and will have two sets of appropriateness ratings of these indications: one by a multidisciplinary panel of experts, representing the disciplines of orthopedics osteopathy, chiropractic, internal medicine, neurology, and family practice, and the second by an all-chiropractic panel. From these ratings, we will develop a medical record abstraction form, a utilization form, and a patient survey. These research instruments will then be used on a random sample of low-back pain patients of chiropractors from a specified geographic area to answer the following research questions:

- What is the use of chiropractic services in the specified geographic area?

- With regard to the chiropractic spinal manipulative therapy of low-back pain what is the level of appropriate care being delivered?

- Does the level of appropriate care vary significantly with the provider? Are there variables predictive of the delivery of appropriate care?

- What are the demographic and general health characteristics of chiropractic patients, and do these differ from patients in the outpatient general medical setting

RAND publications from this project will consist of the following:

1. This volume, which contains the project overview and literature

2. The ratings of appropriateness by the multidisciplinary panel

3. The ratings of appropriateness by the all-chiropractic panel

4. The analysis of the two sets of ratings

5. The research instruments

6. The results of the one-site field study of the use of chiropractic services, the used spinal manipulation, and the chiropractic patients' characteristics.

2. LITERATURE REVIEW

Spinal manipulation as a treatment for musculoskeletal complaints has been practiced centuries, having been described by Hippocrates, Galen, and other Western physicians, as in the writings of comparable

historical figures in Eastern medical history. Many physicians of the 19th century practiced spinal manipulation, and late in that century the two principal philosophies concerning spinal manipulation were developed. Andrew Sull proposed the concept of osteopathy in 1874, and D.D. Palmer formulated the spinal subluxation in 1895. Since then, spinal manipulation has fallen out of favor with physicians and has become virtually the exclusive domain of chiropractors. A analysis of a community-based sample of patients showed that chiropractors delivered of all the manipulative care for which reimbursement was sought, with osteopaths soaring 4% and general practitioners and orthopedic surgeons accounting for the remainder. Recently, however, there seems to be a renewed interest in manipulation on the part of the medical profession (Meade, 1990).

Manipulation encompasses many different techniques. The two most commonly used methods are nonspecific long-lever manipulations and specific short-lever, high-velocity spinal adjustments. It is this second method which is most closely identified with chiropractic practice, although many chiropractors use the long-lever manipulations as well.

This literature review will examine the use of manipulation, of all types, in the treatment of low-back pain. The review initially searched the Index Medicus and computerized database of MEDLINE from 1955 to the present for relevant articles using the Medical Heading terms *chiropractic, manipulation,* and *backache.* It then drew on the bibliography of these articles, as well as a bibliography developed by the CCR. An orthopedist and two chiropractors evaluated the bibliography for completeness and suggested additional sentences including textbooks. No unpublished material was included.

Articles were selected for inclusion if they contained data on the complications, efficacy, use of manipulation for the treatment of low-back pain. Priority was given to research that used a randomized, controlled trial design. Second priority was given to case-series and published in peer-reviewed journals, as well as textbooks. Case reports were excluded except to document complications.

This review is the result of an analysis of 67 articles and 9 books or textbooks published between 1955 and 1989. The table below presents the lumber of studies or articles reviewed, classified by type of research design or source.

This review was prepared to assist back-pain experts in the assessment of the appropriate clinical circumstances for performing spinal manipulation. As such, it summarizes efficacy clinical categories that were used by these experts during the assessment process.

UTILIZATION

Utilization studies of the chiropractic manipulative treatment of low-back pain are few. Most are either regional, lack adequate sampling schemes, or have possibly outdated

Table I

CLASSIFICATION OF RESEARCH ARTICLES ON MANIPULATION FOR BACK PAIN

Category	Number	Percent
Research studies	34	45
Controlled trials	(22)	–
Case-series	(12)	–
Case reports	4	5
Reviews	22	29

Miscellaneous	7	9
Books/textbooks	9	12
Total	76	100

databases that do not allow generalization with confidence to the 1990s. Still, some statements can be made.

The rate of use of chiropractic services is approximately 50 visits per 100 person-year~ used by about 5% of the population (Von Kuster, 1980; Mugge, 1986; Shekelle, 18911. This care is delivered by about 45,000 chiropractors at a cost of approximately $2.4 billion in 1%~ *(FACTS Bulletin,* 1989). Between 32 and 45% of these visits are for low-back pain (Phillip~. 1982; Nyiendo, 1987; Pima Health Systems, 1975; Shekelle, 1991). The patients average - between 5 and 18 visits per episode (Nyiendo, 1987; Phillips, 1982; Shekelle, 1991; Von Kuster, 1980). This type of care is most frequently used by persons who are white, middle - aged, employed, and high-school educated (New Haven Health Care, Inc., 1976; Mugge, 1986, Nyiendo, 1987; Shekelle, 1991). Seven-fold differences in the use rate of chiropractic services have been seen, but the cause or causes of these variations in use remain unknown (Shekelle, 1991).

In one study, chiropractors delivered over 90% of the manipulations for which reimbursement was sought (Shekelle, 1991).

COMPLICATIONS

There has been no systematic study of the frequency of complications from spinal manipulative therapy. A literature review by Ladermann (1980) showed 135 case reports of serious complications, including 18 deaths, from manipulation. These case reports are primarily from the period 1950 to 1980. The number of manipulations received during this 30-year period is unknown, but must number in the tens of millions.

The majority of complications of manipulation can be attributed to the following:

- Misdiagnosis
- Presence of coagulation dyscrasias
- Cervical manipulation
- Presence of herniated nucleus pulposus
- Improper technique.

Misdiagnosis of the patient's condition accounted for 26 of the 135 cases in the report of Ladermann. Most of these involved the unrecognized presence of tumors or metastases. The main complication was delay in diagnosis and treatment. The most serious complication of coagulation dyscrasias was paraplegia from meningeal hematoma. Cervical manipulation had a greater number of complications, of a more serious nature, than did lumbar manipulation. This literature review will not deal with cervical manipulation. The development of the cauda equina syndrome was reported in 20 patients with the presenting symptom of sciatica treated with lumbar manipulation. Many of these patients were manipulated under narcosis or ether anesthesia, which is not acceptable chiropractic technique today. Improper techniques, hale important, is not the subject of this review, nor the focus of the panel discussion

These data suggest that the risk of spinal manipulation is small and that it may vary within subgroups of patients based on their clinical presentation. No firm conclusions may be drawn, however, as there is little available data in the literature.

EFFICACY

The efficacy of spinal manipulation for low-back pain must be assessed by the degree of benefit compared to risk it confers on patients upon whom it is performed. As no survival benefit has ever been shown or claimed, this assessment is necessarily based on subjective or objective evaluations of relief of pain, time to relief of pain, improvement in functional status days lost from work, reduced anxiety, and the like. Additionally, certain physiologic variables, such as flexibility and number of degrees of straight leg raising, have been measured, but in general there is a poor correlation between these measures and functional status.

Ideally, the efficacy of spinal manipulation for the treatment of low-back pain would be assessed by performing a series of randomized, controlled clinical trials upon patients with a variety of different clinical presentations. The patients would need to be selected with an appreciation of the clinical variables predictive of a beneficial result from manipulation. The nonmanipulated group would need to receive some sham treatment to control for the powerful placebo affect of "the laying on of hands." The manipulation itself would be done by an expert clinician and would be defined in terms such that others could reproduce the technique. The assessment of outcome would be performed by observers blinded to the treatment type. The sample size would be large enough to have sufficient power to detect a clinically significant effect should it exist. If a benefit for manipulation was shown,

then manipulation could be compared to other therapies for low-back pain, including bedrest, "back school," corset, and TENS, in another series of randomized trials. Such a research agenda would take many trials, involving many patients, over a considerable period of time. For these reasons and others, the definitive trials of manipulative therapy have yet to be done, as many have noted Brunarski, 1984; Curtis, 1988; Greenland, 1980; Evans, 1985; Hoehler, 1987; Deyo, 1983). Because of the cost and technical difficulties, such a series of trials is unlikely to be completed in the near future. Therefore, as stated by Curtis, the efficacy of spinal manipulation is neither scientifically proven nor disproven at this time.

This review will deal with what is known about the efficacy of spinal manipulation for patients with the following specific clinical problems:

Acute low-back pain
- without neurological findings
- with minor neurological findings
- with major neurological findings
- with sciatic nerve root irritation

Subacute low-back pain
- without neurological findings
- with minor neurological findings
- with major neurological findings
- with sciatic nerve root irritation

Chronic low-back pain
- without neurological findings
- with minor neurological findings
- with major neurological findings
- with sciatic nerve root irritation
- with prior laminectomy.

In addition, this review will deal with some other issues of importance concerning spinal manipulation, including contraindications and treatment intensity and duration.

Before discussing specific clinical syndromes, it is important to mention the limitations, of a general nature, with the controlled trials of manipulation. The initial selection and evaluation of patients for study has varied greatly. Some studies have included all patients presenting to a certain clinic, regardless of duration of pain, mechanism of onset, age, physical exam, etc. Others have carefully restricted patients to those with pain of uniform onset those who have specific findings on physical examination, or other factors. The technique of manipulation is often unclear in many studies and has been performed by a variety of health personnel, including physicians, chiropractors, physiotherapists, and osteopaths. The control groups have varied widely, some receiving virtually no therapy, most receiving a variety of nonspecific measures, such as short-wave diathermy, and a few receiving sophisticated sham manipulations. How these control groups dealt with the placebo effect differed. Outcome measures were not always assessed by an observer blinded to treatment type, introducing bias. In addition, outcome measures have varied between objective measurements (which are of uncertain clinical significance) to subjective measures ranging from simply asking the patient if he feels better to reliable and valid questionnaires dealing with back pain. Lastly, other problems were of sample size, Type II error, and appropriate statistical analysis. Many studies have so few subjects that no conclusion can be drawn. Outcomes measured on ordinal scales have been analyzed with a chi-square test for distribution rather than a test for trend, detracting from statistical power. The Appendix at the end of this literature review summarizes the salient features of the controlled trials of manipulation for back pain.

For the purposes of this review, acute low-back pain is defined as pain of less than 3 weeks duration; subacute low-back pain is that of 3 to 13 weeks duration; and chronic low-back pain is pain of greater than 13 weeks. Sciatic nerve root irritation is defined as typical radicular pain, meaning shooting pain in the posterior thigh or calf, and a straight leg raising sign in the leg with the pain. Minor neurological findings are defined as at least one of the following an asymmetrically decreased ankle reflex, a lower limb dermatomal sensory deficit, or a nonprogressive lower limb muscle weakness. Major neurological findings are a progressive, unilateral lower limb muscle weakness or symptoms or signs of the cauda equina syndrome.

ACUTE LOW-BACK PAIN

Without neurological findings or sciatic nerve root irritation. Two controlled trials included only patients with acute low-back pain without neurological findings or sciatic nerve root irritation (Coyer, 1955; Rasmussen, 1979). Both showed a short-term benefit for manipulation compared to controls of bedrest or diathermy, in terms of time to pain relief. In the study by Coyer, there was a steadily decreasing advantage for the manipulated group at 3 and 6 weeks. Rasmussen's study is limited by its 2-week follow-up and its nonblinded assessment of results. An additional controlled trial by Doran (1975), which excluded patients with neurological findings or sciatic nerve root irritation but included patients with acute, subacute, and chronic pain, did not show any benefit for manipulation when compared to three control groups of physiotherapy, a corset, or bedrest. Hoeh.ler (1987) reanalyzed these data using a test for trend (rather than the statistically weaker chi-square test for distribution and showed a benefit of manipulation for improvement of pain at 3 weeks.

The study by Bergquist (1977) included patients with both acute and subacute low-back pain; however, 83% of patients had pain of less than 3 weeks duration. Patients with neurological findings were excluded. Sciatica was not excluded, though only 27% had sciatic nerve root irritation. Bergquist found no difference between "combined physiotherapy," which included manipulation to hypomobile joints and "back school," but both were significantly better than "placebo" in shortening the time to total recovery. No difference was found between groups in the rate of development of chronic pain, or the rate of recurrences of back pain within 1 year.

In other studies, Maitland (1957) reported his noncontrolled case series of 220 patients. Patients with acute low-back pain, without neurological findings, constituted 51% of the total. Twenty patients were treated with bedrest, yielding a 50% response rate requiring an average of 23 days treatment. His next 75 patients, plus six "failures" from the bedrest group, were treated with manipulation, yielding a 96% response rate in an average of 4.5 treatments. Potter (1977) reported a response rate or 93% for patients with acute low-back pain and no leg pain or neurological findings (N115; average number of treatments = 3.3) in his large case series.

In summary, the literature supports the use of spinal manipulation or bedrest for patients with acute low-back pain without evidence of neurological involvement or sciatic nerve irritation, with spinal manipulation possibly conferring a short-term but significant benefit in pain relief.

Without minor neurological findings but with sciatic nerve root irritation. One study restricted its patients to those with acute back pain without minor neurological findings, but did include those with sciatic leg pain, and presumably sciatic nerve root irritation as well

(Farrell, 1982). In this study, there was a short-term benefit for the manipulated group compared to a control group that received diathermy, exercises, and instruction; the difference was gone by 3 weeks.

Mathews (1987) included both patients with acute and subacute pain; otherwise, the sample patients were without minor neurological findings, but some did have sciatic nerve root irritation. There was an impressive short-term benefit for those patients with straight leg raising signs at 2 weeks. Follow-up at 1 year showed no difference between the manipulated group and the comparison group, which received infrared heat.

In the trial by Bergquist (1977), 83% of patients had acute pain and 27% of patients had sciatic nerve root irritation. "Back school" or "combined physiotherapy" (which included manipulation). were significantly better treatments than was diathermy (15.8, 14.8, and 28.7 days to recovery, respectively). This study is discussed in more detail in the section above entitled 'Without Neurological Findings or Sciatic Nerve Root Irritation."

In summary, the literature is insufficient to support or refute the use of spinal manipulation for patients with acute low-back pain and sciatic nerve root irritation. The limited data available suggest that for this class of patients, like those with acute low-back pain but without sciatic nerve root irritation, spinal manipulation may offer a short term benefit in terms of pain relief.

With minor neurological findings and without sciatic nerve root irritation. No study confined its patient population to only those with acute low-back pain with minor neurological findings without sciatic nerve root irritation. Meade's two studies (1986, 1990), which had patients with acute, subacute, and chronic back pain,

included those with minor neurologic findings and excluded those with sciatic nerve root irritation (but not leg pain alone). Both studies showed a statistically significant benefit for "chiropractic care" (which. almost always included manipulation) vs. "medical care" (which may have included nonchiropractic manipulation as well) in terms of the Oswestry Score, a reliable and valid instrument to assess functional status. The later study showed the benefit to be both durable (up to 2 years follow up) and equivalent for patients with acute (pain less than 1 month), subacute, and chronic (pain greater than 1 month) back pain.

In summary, the literature is insufficient to support or refute the use of spinal manipulation for patients, with acute low-back pain and minor neurological findings without sciatic nerve root irritation.

With minor neurological findings and sciatic nerve root irritation. There is one controlled trial of manipulation for patients with acute low-back pain and minor neurological findings who also all presumably had sciatic nerve root irritation (Nwuga, 1981). ~These patients also had disc protrusion confirmed by myelography. There was a significantly 'shorter time to pain relief in the manipulated group vs. a control group, which received diathermy. There was improvement in some, but not all, measured physiologic variables as well. Another study (Hadler, 1987) included patients with generally acute pain (but by our definition included some patients with subacute pain) and patients with signs of sciatica and presumably sciatic nerve root irritation. Overall, no benefit was shown for manipulation vs. mobilization; however, stratified analysis showed a benefit for manipulation in patients with symptoms of between 2 and 4 weeks. In other studies, Maitland (1957) reported a response rate of only 16% to 19% in patients with acute low-back pain and pain radiating down the leg. In contrast, Potter (1977) reported

improvement in 48% of his patients with acute low-back pain and neurological findings.

In summary, there is conflicting evidence in the literature on the use of spinal manipulation for patients with low-back pain with minor neurological findings and sciatic nerve root irritation.

With major neurological findings. There has been no study, controlled or uncontrolled, describing the manipulative treatment of patients with acute low-back pain and major neurological findings.

Additional issues. Vertebral joint fixation, sacroiliac joint fixation, and hypertonic contraction of the paraspinous muscles correspond to the syndromes described by KirkaldyWillis and Cassidy (1988) as "Definite and Certain Indications for Manipulation." No controlled trials support this statement. Kirkaldy-Willis and Cassidy report their case series of patients with mainly chronic pain; 80% to 90% of the patients with vertebral or sacroiliac joint fixation responded favorably. Numerous anecdotal reports by Maigne and others document the nearly instantaneous relief of pain due to the third indication (hypertonic contraction of the paraspinous muscles). Chiropractic teaching states that the presence of hypertonic contraction of the paraspinous muscles implies joint fixation.

Spinal manipulation has not been shown to reduce a herniated nucleus pulposus physically. In fact, two studies (Wilson, 1952; Chrisman, 1964) showed that there was no difference myelographically in disc protrusion before and after manipulation. Many patients reported an improvement in symptoms despite the apparent absence of a change in their disc protrusion. In the Chrisman study, the majority of patients who had chronic pain had an "excellent" or "good" improvement in pain relief *(35139);* however 10 of these ultimately had recurrences requiring operations.

The Quebec Task Force, which dealt with the usefulness of a variety of conservative modalities as treatments for low-back pain, classified "mobilisation/manipulation" as contraindicated on the basis of scientific evidence" for lumbar spinal disorders with radicular compression presumed or confirmed. They cite no references to support this statement, however. Interestingly, the Task Force did not feel manipulation was contraindicated in the presence of confirmed spinal stenosis.

Central spinal stenosis has not been subjected to a controlled trial of manipulative therapy. Kirkaldy-Willis and Cassidy (1988) feel it responds significantly worse to manipulation than other indications; they report 18% of 11 patients were "symptom free" and an additional 18% had only "mild intermittent pain" after manipulation. These 11 patients were "a small, select group of patients with central spinal stenosis who were unfit for surgery." Cox (1990) states that central spinal stenosis or medial disc protrusion responds poorly to manipulation; he also states that the presence of certain major neurologic findings, such as difficulty walking and rectal difficulties, in the presence of central spinal stenosis or a-medial disc protrusion, is an indication for immediate surgical referral.

SUBACUTE LOW-BACK PAIN

Concerning the appropriateness of treating patients with subacute low-back pain with spinal manipulation, the presence or absence of prior manipulative treatment for the current episode of pain and the response to that treatment is felt by many manipulating physicians to be clinically important. Because of this perception, the appropriateness ratings for subacute low-back pain are divided into two clinical chapters based on prior treatment for the current episode of pain. Because of a lack of scientific studies examining efficacy in this way, this section of the literature review will deal with subacute back pain with or without the presence of neurological findings and sciatic nerve root irritation.

Without neurological findings or sciatic nerve root irritation. No controlled study dealt with patients who have only subacute low-back pain without neurological findings or sciatic nerve root irritation. However, four controlled studies dealt with patients without neurological findings who had either subacute or acute and chronic pain. These results may be useful in assessing the appropriateness of spinal manipulation for subacute low-back pain. The study by Doran (1975) included patients with low-back pain of any duration. Doran's analysis using a chi-square test of distribution showed no benefit for manipulation when compared to any of three control groups. A later reanalysis of these data by Hoehler 19671 using a statistically more powerful test for trend showed a significant benefit for manipulation at 3 weeks (45% vs. 35% improved). Evans (1978) included patients with both subacute and chronic pain who had no signs of femoral or sciatic root compression. Minor neurological findings were presumably excluded, as well as signs of nerve root compression. There was a significant benefit for manipulation on overall pain scores at 3 weeks when compared to treatment with codeine alone, but the

crossover nature of this study and a randomization failure make the validity questionable. Gibson (1985) included patients with both 3ubacute and chronic pain without neurological signs and randomized them to receive diathermy or osteopathic treatment including manipulation. No difference was seen between Groups. Lastly, Waagen (1986) reported on 19 patients with subacute or chronic back pain' 'without neurological findings or sciatic nerve root irritation, who were randomly assigned to manipulation vs. a sham. There was a statistically significant benefit for manipulation on changes in levels of pain as assessed on the Visual Analogue Scale (manipulation = 1.7 cm difference, controls = 0.6 cm difference) at 2 weeks. This study suffered from 10 dropouts (34%) from those initially selected.

In summary, the literature contains conflicting evidence regarding the use of spinal manipulation for patients with subacute low-back pain without neurological findings or sciatic nerve root irritation. The majority of studies suggest that spinal manipulation may have a short-term benefit in terms of pain relief for this class of patients.

Without minor neurological findings but with sciatic nerve root irritation. No controlled study limited its patient population to patients with subacute low-back pain with. out minor neurological findings but with sciatic nerve root irritation. However, two studies may have included this kind of patient, but did not stratify the analysis to answer this question. Mathews (1987) randomized patients with both acute and subacute low-back pain, without minor neurological findings, to manipulation or infrared heat. The analysis was stratified on the presence or absence of straight leg raising signs and/or femoral nerve stretch test. Patients with these signs showed the greatest improvement for manipulation, with a 30% advantage (to complete recovery) for manipulation at 6 days (based on both clinical assessment and patient self-report on the Visual Analogue

Scale). Patients without these signs improved considerably in 2 weeks in both the manipulated group and the nonmanipulated group, with a nonsignificant trend favoring manipulation. The advantage of manipulation was gone by 1 year. The study by Zylbergold (1981) excluded patients with minor neurologic findings; the duration of pain and the presence of sciatic nerve root irritation is unknown. There was no benefit for manipulation when compared to heat and physical therapy in functional status among the 28 patients in the study.

In summary, the literature is insufficient to support or refute the use of spinal manipulation for patients with subacute low-back pain without minor neurological findings but with sciatic nerve root irritation.

With minor neurological findings but without sciatic nerve root irritation. No study examined the benefit of spinal manipulation for patients with subacute low-back pain with minor neurologic findings but without sciatic nerve root irritation. The two studies by Meade most nearly address this question. The studies included patients with both acute, subacute, and chronic low-back pain. Patients with minor neurologic findings were not excluded; those with evidence of nerve root compression were. There was a significant improvement in Oswestry score in both studies for those patients randomized to "chiropractic care" vs. "medical care." The later study showed the benefit to be sustained, up to 2 years at least. Analysis of the later study, stratified on duration of pain greater or less than 1 month, showed no difference in the benefit for chiropractic care for those with acute pain vs. those with subacute or chronic pain.

In summary, the literature is insufficient to either support or refute the use of spinal manipulation for patients with subacute low-back pain and minor neurological findings but without sciatic nerve root irritation.

With minor neurological findings and sciatic nerve root irritation. The study by Coxhead (1981) involved mainly patients with subacute low-back pain who all had sciatica 'and presumably included those with minor neurologic findings as well as those with sciatic nerve root irritation. The results showed a statistically nonsignificant trend toward a benefit for manipulation as compared to three control groups treated with a corset, "back school" or traction at 4 weeks; by 4 months the trend was gone. A later reanalysis of these data by Hoehler (1987), using a more powerful statistical test for trend, showed a benefit for manipulation at 4 weeks (82% vs. 73% improved). Two other controlled trials had patients with minor neurological findings and sciatic nerve root irritation and included subacute low-back pain among others (Hoehler, 1981; Hadler, 1987). The study by Hadier, which was stratified on duration of pain less than 2 weeks or between 2 weeks and 4 weeks duration, showed a benefit for manipulation only in those patients with pain of between 2 and 4 weeks duration (50% greater reduction in pain score at 2 weeks of treatment, compared to controls receiving mobilization). Hoehler's study, which may have included patients with minor neurologic findings and/or sciatic nerve root irritation but was not stratified in that way, showed an immediate benefit for manipulation, which was gone at 3 week follow-up.

In summary, the literature is limited but probably supports the use of spinal manipulation for patients with subacute low-back pain with minor neurological findings and sciatic nerve root irritation, its use conferring a slight short-term benefit in pain relief.

With major neurological findings. No study, controlled or uncontrolled, has described the manipulative treatment of patients with subacute low-back pain and major neurological findings.

Additional issues. Concerning prior treatment, it is many chiropractors' clinical belief that patients with evidence of joint fixation and a recent episode of back pain are at higher risk to relapse than those without evidence of joint fixation. Because of this, they believe that these patients should undergo manipulation to relieve the undesirable joint restriction, with the belief that this will bring a more durable and lasting improvement in symptoms. This series of beliefs has not been subjected to rigorous study.

With regard to the frequency of treatment for the 'patient undergoing manipulation, please refer to the section on "Treatment Duration" for a discussion of the literature.

Spinal manipulation has not been shown to reduce a herniated nucleus pulposus physically. Please refer to the discussion under Additional Issues in the section on acute low-back pain for a review of the literature.

The Quebec Task Force concluded that spinal manipulation is contraindicated in the presence of radicular compression. Please see Additional Issues in the section on acute low back pain for more discussion of this.

Central spinal stenosis has not been subjected to a controlled trial of manipulative therapy. The discussion under Additional Issues in the section on acute low-back pain analysis this topic in more detail.

CHRONIC LOW-BACK PAIN

Analogous to patients with subacute low-back pain, many manipulating physicians feel that the type of and response to prior treatment is important in determining the likelihood of a beneficial effect of spinal manipulation for patients with chronic low-back pain. Reflecting this opinion, the appropriateness ratings for chronic low-back pain are divided into three clinical chapters based on prior treatment, although no scientific studies have examined the object this way. Therefore, this section will deal with chronic back pain with or without the presence of neurological findings and sciatic nerve root irritation. Two case series dealing with response to prior laminectomy will be reviewed.

Without neurological findings or sciatic nerve root irritation. No controlled tri dealt only with patients with chronic low-back pain without neurological signs or sciatic nerve root irritation, treated with manipulation alone. The study by Ongley (1987) included an injection of an experimental "proliferant" to the group treated with manipulation, and the effect of manipulation is impossible to determine. The trials of Evans 1978, Gibson (1985), and Waagen (1896) dealt with patients without neurological findings or sciatic nerve root irritation and had subacute or chronic back pain. manipulation at 3 weeks when compared to controls (45% vs. 35% Evans trial is confounded by the crossover design; Gibsons study showed no benefit; and Waagens study showed a benefit for manipulation, as compared to sham treatment, with improvement measured on the Visual Analogue Scale at 2 weeks. The study by Doran, which excluded minor neurologic findings and sciatic nerve root irritation but took patients with pain of all duration, showed a benefit for manipulation at 3 weeks when compared to controls (45% vs 35% improved). In other studies, Potter (1977) reported an improvement in 64% of patients with chronic low-back

pair, and no leg involvement. Kirkaldy-Willis and Cassidy (1988) report their case series on patients with chronic pain; between 45% and 92% had good recovery, depending on their precise diagnosis.

In summary, the literature gives conflicting evidence on the value of spinal manipulation for patients with chronic low-back pain without neurological findings or sciatic nerve root irritation.

Without minor neurological findings but with sciatic nerve root irritation. No controlled trials examined the effect of manipulation in patients with chronic low-back pain without minor neurologic findings but with sciatic nerve root irritation.

With minor neurological findings but without sciatic nerve root irritation. The only controlled trial to examine this question is the second study of Meade (1990). This study randomized 375 of 717 patients with low-back pain of any duration, some of whom presumably had minor neurologic findings but none of whom had sciatic nerve root irritation, to "chiropractic care" or "medical care." The chiropractic-care group as a whole had significant improvements relative to the medical-care group in Oswestry Score at 6, 12, and 24 months. Stratified analysis showed that patients with pain of more than 1 month's duration responded equivalently to those with pain of shorter duration.

With minor neurological findings and sciatic nerve root irritation. Arkuszewski (1986) has reported the single controlled trial that included patients with only chronic low-back pain and minor neurological findings. Time to pain relief was improved by manipulation as compared to massage (3.1 vs. 3.8 weeks). More impressively, at 6 months 60% of the manipulated group had returned to work compared to 36% of the control group. These results are

limited by the nonrandom assignment of treatment groups and the non-blinded assessment used. Glover (1974), and possibly Edwards (1969) and Sims-Williams (1978), also reported controlled trials of patients that included those with chronic pain and minor neurological findings with sciatic nerve root irritation. These studies showed a short-terra benefit for manipulation that diminished at later follow-up. This diminution was usually due to improvement of the control group rather than deterioration of the manipulated group. In other studies, Mensor (1955), Chrisman (1964), and Kuo 1986 all reported case series of patients with chronic low-back pain and minor neurological findings with sciatic nerve root irritation. In Chrisman's study the patients also had documented disc protrusions. In Mensor's series of 205 cases, between 45% and 64% had excellent or good results, depending on insurance status (private or worker's compensation). The majority of the patients in Chrisman's study had an "excellent" or "good" improvement in pain relief (35/39); however, 10 of these ultimately had recurrence requiring operation. Kuo's series of 517 patients treated over 8 years yielded a 76.8% satisfactory response rate, with 14.1% recurrences. Operative findings in patients unresponsive to manipulation or who relapsed tended to show a central disc protrusion or a "huge" disc protrusion. Potter (1977) reported a 36L~ improvement in patients with chronic low-back pain and neurological findings. Lastly, in the case series of Kirkaldy-Willis and Cassidy (1988), chronic back pain from lesions associated with minor neurological findings and sciatic nerve root irritation had a response rate of between 50 and 60%.

In summary, the literature is not conclusive concerning the use of spinal manipulation patients with chronic low-back pain with minor neurological findings and sciatic nerve.

With major neurological findings. No study, controlled or uncontrolled, has described the manipulative treatment of patients with chronic low-back pain and major neurological findings.

With prior laminectomy. There are no controlled trials of manipulation in patients with chronic low-back pain who have had previous laminectomy. Two case series, however gave somewhat conflicting results. In the series by Potter (1977), prior laminectomy did not alter the response of patients to manipulation with chronic low-back pain, with or without neurological findings. Kirkaldy-Willis and Cassidy (1988), however, report a 72% response rate in patients without prior laminectomy, and a 64% response rate in patients with prior laminectomy for patients with chronic back pain of all kinds.

Additional issues. With one exception, all studies of back pain that have shown duration of symptoms to be a predictor of response to treatment with spinal manipulation have shown the duration of symptoms to be inversely related to the likelihood of response. Bronfort (1986) reported that patients with a shorter duration of symptoms were more likely to respond to chiropractic treatment (15% vs. 65% not cured within 6 months for patients with less than 7 days of initial pain vs. more than 28 days). Similar results were shown by Maitland (1957), Glover (1974), Evans (1978), Potter (1977) and Sims-Williams (1978).

With regard to biomechanical and psychosocial stress, Bronfort showed that the presence of psychological overlay (as defined by the hysteria and hypochondriasis scores on the MMPI), as well as the presence of improper working posture, were associated with poorer response to

chiropractic manipulation. The association of these factors with troublesome Chronic back pain is well recognized in the medical community (K.irkaldy-Wihis, 1988; Frymoyer, 1988).

As discussed in the section on acute low-back pain, spinal manipulation has not been known to reduce physically a herniated nucleus pulposus. Please refer to the discussion on Additional Issues in the section on acute low-back pain for a review of the literature.

The Quebec Task Force concluded that spinal manipulation is contraindicated in the presence of radicular compression. This is also discussed under Additional Issues in the section on acute low-back pain.

Central spinal stenosis has not been subjected to a controlled trial of manipulative therapy. The discussion under Additional Issues in the section on low-back pain analyzes this topic in more detail.

OTHER CONCERNS

Treatment Duration

The scientific literature is not helpful in deciding when a patient should stop being treated with spinal manipulation, either with respect to improvement or worsening of symptoms. The literature reports controlled trials or case series with between 1 and 19 sessions of manipulation lasting anywhere from a single day to 2 months. it is unclear how many, if any, manipulations are necessary after the patient has become pain-free. There is more guidance concerning the patient who is not improving. The utilization guidelines developed by Hansen (1988) define indications for a second opinion to be:

- Treatment of three times a week that exceeds 4 weeks
- No objective or subjective signs of improvement, or worsening of condition, in first 2 weeks.

These recommendations are based on consensus among clinicians and have no experimental evidence to support them. They also only apply to acute or subacute low-back pain from a recent injury. There is no guidance with respect to chronic back pain or to pain not due to an injury.

The Ohio State Chiropractic Association, in their guidelines for utilization, list the pa. rameters in Table 2 as a general guide for care.

La Brot (1989), in his privately published monograph, suggested the following number of visits and treatment duration listed in Table 3.

All of these recommendations, whether by individuals or by consensus, are based on clinical experience and opinion, without rigorous scientific support.

Table 2 -

OHIO STATE CHIROPRACTIC ASSOCIATION GUIDELINES FOR FREQUENCY AND DURATION OF TREATMENT

Conditions	Frequency (number of treatments /time period)	Duration
Acute		
Mild	daily to 3/week	up to 30 days
Moderate	3/week	up to 30 days

	1–2/month	up to 3 months
Severe	3/week	up to 3 months
	1-2/month	up to 5 months
Cbronic		
Mild	3/week	up to 2 months
	1–2/month	up to 6 months
Moderate	3/week	up to 2 months
	1–2/month	up to 12 month
Severe	3/week	up to 4 months
	1–2/month	up to 18 month

Table 3

LA BROTS GUIDELINES FOR FREQUENCY AND DURATION OF TREATMENT

Injuries	Number of Office Visits	Treatment Duration
Traumatic		
Mild	9–17	4 weeks
Moderate	19–45	up to 6 months
Severe	39–68	up to 12 month
Non-Traumatic		
Mild	5-12	4 weeks
Moderate to severe	14–28	up to 12 weeks

Clotting Disorders

In many textbooks and reviews of chiropractic, the presence of clotting disorders ~specifically in reference to patients taking therapeutic anticoagulants) is listed as a contraindication to manipulation. In reviews of the case reports of complications of manipulation, four cases, two serious (paraplegia from meningeal hematoma) and two nonserious petechial rash or ecchymosis), were reported in patients with a clotting disorder who received spinal manipulation. As with other complications of spinal manipulation (see Complications), there is no way of knowing either the total number of complications due to clotting disorders or the

number of patients with clotting disorders undergoing manipulation. Thus there is no way of estimating the frequency with which adverse outcomes occur in this patient population.

Abdominal Aortic Aneurysm

As with clotting disorders, this is listed in many textbooks and reviews of chiropractic as a contraindication to manipulation. No case reports of complications due to abdominal aortic aneurysm have been found.

Spondylolisthesis

No controlled trials exist to determine the prognostic influence of spondylolisthesis on reponse to manipulation for back pain. Mirau (1987) reports that the response of patients with chronic low-back pain with and without spondylolisthesis is equivalent. There is no evidence that spinal manipulation can reduce a spondylolisthesis.

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No controlled trials exist to determine the prognostic influence of spondylolisthesis on response to manipulation for back pain. Mirau (1987) reports that the response of patients with chronic low-back pain with and without spondylolisthesis is equivalent. There is no evidence that spinal manipulation can reduce a spondylolisthesis.

Appendix
CONTROLLED TRIALS OF SPINAL MANIPULATION

This appendix summarizes the salient features of the controlled trials of manipulation for treatment of back pain.

Author [1,2]	Coyer (1955)(Britain)
Duration of Pain [3]	A
Sciatic Pain/SNI [4,5]	Excluded
Minor Nuerologic Findings [6]	Excluded
Palpatory Findings [7]	None
Manipulation Defined (Type)	Yes (Cyriax)
#Manipulated/Total Sample [8]	
(# of Manip.) [9]	76/136 (1)

Results 50% of manipulated group pain free et 1 week compared to 27% of controls treated with bedrest; values for 6 weeks were 88% and 72%, respectively

Author	Edwards (1969) (Australia)
Duration of Pain	Not Defined
Sciatic Pain/SNI	Included/presumably included
Minor Nuerologic Findings	Presumably Included
Palpatory Findings	None
Manipulation Defined (Type)	Yes (Maitland)
#Manipulated/Total Sample	
(# of Manip.)	92/184 (13 max.)

Results No overall difference between manipulation and heat/massage, but manipulation improved those with sciatic pain and provided relief in half (4.8 vs. 9.7) the number of treatments

Author	Glover (1974) RCT(Britain)
Duration of Pain	A/S+C
Sciatic Pain/SNI	Included/not stated

Minor Nuerologic Findings	Included
Palpatory Findings	Yes
Manipulation Defined (Type)	Yes (Rotational)
#Manipulated/Total Sample (# of Manip.)	43/84 (1)

Results - In general no difference between manipulation and diathermy vs. diathermy alone, manipulation provided better pain relief for those with <7 days of pain and first attach of back pain (61% vs/ 42% mean pain relief at 3 days)

Author	Doran (1975) RCT (Britain)
Duration of Pain	A, S, C
Sciatic Pain/SNI	Excluded
Minor Nuerologic Findings	Excluded
Palpatory Findings	No
Manipulation Defined (Type)	No
#Manipulated/Total Sample (# of Manip.)	116/456 (6 avg.)

Results No difference between manipulation, physiotherapy, corset, and analgesics, using chi-square; later analysis by Hoehler (1987) showed statistical benefit for manipulation (45% vs. 35% improved at 3 weeks)

Author	Bergquist (1955) RCT (Sweden)
Duration of Pain	Mainly A, some S
Sciatic Pain/SNI	Included, included
Minor Nuerologic Findings	Presumably Excluded
Palpatory Findings	Yes
Manipulation Defined (Type)	Yes (Janda)
#Manipulated/Total Sample (# of Manip.)	72/217 (variable)

Results "Combined physiotherapy" including manipulation or "back school" better than diathermy (time to recovery 15.8, 14.8, and 28.7 days, respectively)

Author	Evans (1978) RCT (Britain)
Duration of Pain	S, C
Sciatic Pain/SNI	Included/excluded
Minor Nuerologic Findings	Probably Excluded
Palpatory Findings	No
Manipulation Defined (Type)	Yes (Rotational)
#Manipulated/Total Sample (# of Manip.)	32 (3 weeks)

Results Statistically significant improvement for manipulation vs. codeine in overall pain score for each group, older patients did better than younger, but crossover design, randomization failure make conclusions questionable.

Author	Sims-Williams (1978) RCT (Britain)
Duration of Pain	Not specified
Sciatic Pain/SNI	Included/not stated
Minor Nuerologic Findings	Included
Palpatory Findings	Yes
Manipulation Defined (Type)	Yes (Maitland)
#Manipulated/Total Sample (# of Manip.)	47/94 (14 max.)

Results Significant improvement for manipulation vs. diathermy in return to light work at one month; effect was gone by three months; pain <1 month responded better

Author	Rasmussen (1979) (Denmark)
Duration of Pain	A
Sciatic Pain/SNI	Excluded
Minor Nuerologic Findings	Probably excluded
Palpatory Findings	No
Manipulation Defined (Type)	Yes (Rotational)
#Manipulated/Total Sample	

(# of Manip.)	12/24 (2 weeks)

Results Distinct benefit for manipulation vs. diathermy though non-blinded assessment (10/12) improved with manipulation vs. 3/12 in control group)

Author	Hoehler (1981) RCT (USA)
Duration of Pain	52% A 17% C
Sciatic Pain/SNI	Not stated
Minor Nuerologic Findings	Not Stated
Palpatory Findings	Yes
Manipulation Defined (Type)	Yes (Rotational)
#Manipulated/Total Sample (# of Manip.)	56/95 (5 avg.)

Results Immediate benefit of manipulation vs. sham (84% vs. 68% pain relief); gone by 3 weeks; sophisticated control group.

Author	Coxhead (1981) RCT (Britain)
Duration of Pain	Mainly S
Sciatic Pain/SNI	Only/Presumably Included
Minor Nuerologic Findings	Presumably Included
Palpatory Findings	No
Manipulation Defined (Type)	Yes (Maitland)
#Manipulated/Total Sample (# of Manip.)	155/322 (14 max.)

Results Manipulation possibly slightly better than corset, back school, or traction, certainly better than no treatment, at 4 weeks; gone at 4 months. Later reanalysis by Hoehler (1987) showed statistically significant benefit of manipulation (82% vs. 73% improved) at 4 weeks

Author	Zybergold (1981) RCT (Canada)
Duration of Pain	Not stated
Sciatic Pain/SNI	Not stated
Minor Nuerologic Findings	Excluded
Palpatory Findings	No
Manipulation Defined (Type)	No
#Manipulated/Total Sample (# of Manip.)	8/28 (2/week for 4 wk)

Results Manipulation no better than heat and physical therapy or traction in functional status at 4 weeks

Author	Nwuga (1982) RCT (Nigeria)
Duration of Pain	A
Sciatic Pain/SNI	Only/presumably Included
Minor Nuerologic Findings	Included
Palpatory Findings	No
Manipulation Defined (Type)	Yes (oscillatory rotation)
#Manipulated/Total Sample (# of Manip.)	26/51 (12 max.)

Results Significant benefit for manipulation vs. diathermy for total rotation and straight leg raising compared to baseline for each group, NOT between groups. Significantly shorter time to pain relief for manipulation group (121 min. vs. 160 min. combined total treatment time)

Author	Farrell (1982) RCT (Australia)
Duration of Pain	A
Sciatic Pain/SNI	Included /presumably included
Minor Nuerologic Findings	Excluded
Palpatory Findings	No
Manipulation Defined (Type)	Yes (Maitland)

#Manipulated/Total Sample (# of Manip.)	24/48 (9 max.)

Results Short term benefit for manipulation vs. diathermy, exercises, and instructions; shorter time to pain relief (3.5 vs. 5.8 treatments); no difference in groups at 3 weeks

Author	Godfrey (1984) RCT (Canada)
Duration of Pain	A
Sciatic Pain/SNI	Not stated
Minor Nuerologic Findings	Not Stated
Palpatory Findings	Yes
Manipulation Defined (Type)	Yes (Maigne)
#Manipulated/Total Sample (# of Manip.)	22/81 (5 max.)

Results Trend toward benefit from manipulation vs. massage; later reanalysis by Hoehler (1987) showed statistically significant benefit for manipulation for back mobility (30% vs. 15%), but not overall symptomatology at 2 weeks; chiropractor and M.D. manipulator

Author	Gibson (1985) RCT (Britain)
Duration of Pain	S, C
Sciatic Pain/SNI	Probably excluded
Minor Nuerologic Findings	Excluded
Palpatory Findings	No
Manipulation Defined (Type)	Yes (Minimal rotation)
#Manipulated/Total Sample (# of Manip.)	41/109 (4 max)

Results No benefit in subjective or objective outcomes immediately and at 2, 4, and 12, weeks; control group received diathermy

Author	Arkuszewski (1986)(Poland)
Duration of Pain	C
Sciatic Pain/SNI	Included/included
Minor Nuerologic Findings	Included
Palpatory Findings	No
Manipulation Defined (Type)	No
#Manipulated/Total Sample (# of Manip.)	50/100 (6 avg., 10 max)

Results Time to pain relief improved for manipulation vs. massage (3.1 vs. 3.8 weeks); at 6 months, 60% of manipulated group vs. 36% of control group had returned to old jobs; results limited by nonblinded assessment

Author	Waagen (1986) RCT (USA)
Duration of Pain	S, C
Sciatic Pain/SNI	Excluded
Minor Nuerologic Findings	Excluded
Palpatory Findings	No
Manipulation Defined (Type)	Yes (Chiropractic adjustments)
#Manipulated/Total Sample (# of Manip.)	9/19 (4 avg)

Results Benefit for manipulation vs. sham on Visual Analogue Scale measurements of pain immediately and at 2 weeks (0.6 and 1.7 difference between groups on VAS immediately and at 2 weeks, respectively); manipulations were given by chiropractor; 10 dropouts from enrollees

Author	Meade (1986) RCT (Britain)
Duration of Pain	A, S, C
Sciatic Pain/SNI	Not excluded/ excluded
Minor Nuerologic Findings	Included

Palpatory Findings	No
Manipulation Defined (Type)	No
#Manipulated/Total Sample (# of Manip.)	23/50 (unknown)

Results Mean improvement in Oswestry Score between 0 and 6 weeks was 3.0 for those treated at medical clinic with exercises, traction, hydrotherapy, and possibly manipulation vs. 10.7 for those treated at chiropractic clinic; chiropractic manipulation

Author	Ongley(1987) RCT (USA)
Duration of Pain	C
Sciatic Pain/SNI	Excluded
Minor Nuerologic Findings	Not excluded
Palpatory Findings	No
Manipulation Defined (Type)	Yes (Sacroiliac lumbar roll)
#Manipulated/Total Sample (# of Manip.)	40/81 (1)

Results Experimental group had significantly better outcomes on validated questionnaire; addition of injection of "proliferant" to experimental subjects makes interpretation of effect of manipulation alone difficult

Author	Hadler(1987) RCT (USA)
Duration of Pain	Mainly A, some S
Sciatic Pain/SNI	Included/presumably included
Minor Nuerologic Findings	Included
Palpatory Findings	No
Manipulation Defined (Type)	Yes (Lumbar rotation)
#Manipulated/Total Sample (# of Manip.)	28/54 (1)

Results No overall difference in balidated back pain questionnaire between manipulation and mobilization, but

patients with pain of 2 to 4 weeks duration achieved a 50% reduction in pain score more rapidly with manipulation than with mobilization

Author	Mathews(1987) RCT (Britain)
Duration of Pain	A, S
Sciatic Pain/SNI	Included/included
Minor Nuerologic Findings	Excluded
Palpatory Findings	Yes
Manipulation Defined (Type)	Yes (Rotation; straight thrust)
#Manipulated/Total Sample (# of Manip.)	165/291 (up to 10)

Results Benefit for manipulation in patients with straight leg raising signs both subjectively and objectively at 2 weeks (30% difference in recovery rate); controls were given infrared heat. Patients without straight leg raising signs improved greatly but not significant; no difference at one year

Author	Meade(1990) RCT (Britain)
Duration of Pain	A, S, C
Sciatic Pain/SNI	Not Excluded/ excluded
Minor Nuerologic Findings	Presumably included
Palpatory Findings	No
Manipulation Defined (Type)	No
#Manipulated/Total Sample (# of Manip.)	375/717 (9 avg.)

Results Comparison of "chiropractic care" vs. "medical clinic care" for patients with back pain; 99% of chiropractic patients were manipulated, some medical patients were manipulated as well. Significantly greater improvement in Oswestry Score in chiropractic group at 6, 12, and 24 months; improvement in physiologic variables

greater for chiropractic group as well. Patients with subacute and chronic pain improved similarly to those with acute pain.

NOTES:

1. First author and year of publication are provided for each study.
2. Studies designated RCT had random allocation of subjects
3. A=Acute; S=Subacute; C=Chronic.
4. Inclusion or exclusion of patients with with typical sciatic pain is listed; "only" refers to studies which included only patients with sciatic pain.
5. SNI means sciatic nerve root Irritation, defined as typical sciatic pain and a positive Ipsilateral straight leg raising sign (positive – pain distal to knee).
6. Minor neurologic findings are one of the following-, decreased ankle reflex, dermatomal sensory deficit, or nonprogressive motor weakness.
7. Palpatory findings refers to the use of specific physical findings thought to be Indicative of joint fixation as a criterion for entry.
8. "# manipulated" refers to the number of subjects in the manipulation group.
9. " #of manip." refers to the number of manipulative sessions during the study.

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

American Chiropractic Association, Inc., et al.,	)	
	)	CASE NO. 1:00 CV 00113
Plaintiffs	)	
	)	Judge James P. Jones
v.	)	
	)	
Trigon Healthcare, Inc., et al.)		
	)	
Defendants.	)	

DECLARATION OF
SCOTT HALDEMAN, M.D., Ph.D., D.C.

1. My current position and qualifications are set out in my expert witness report served in this action and attached hereto as Exhibit A. That report is accurate and based on reliable and generally accepted or otherwise reliable sources.

2. I have reviewed the declaration of J. Lawrence Colley dated August 6, 2002, and \particularly paragraphs 7 through 12 of that affidavit concerning The Agency for Health Care Policy and Research (AHCPR) Clinical Practice Guideline No. 14, Acute Low Back Problems in Adults, AHCPR Publication No. 95-0642,and Quick Reference Guide for Clinicians, AHCPR Publication No. 95-0643, and Trigon's Clinical Practice Guideline Managing Low Back Problems in Adults. I served on the AHCPR Panel on Acute Low Back Pain in Adults.

3. Dr. Colley states, at paragraph 8, that the flow chart in Trigon's clinical practice guideline is more favorable to chiropractors than the flow charts of the AHCPR

publications because the AHCPR flow charts do not mention manipulation. This statement is profoundly misleading. The AHCPR's flow charts, page 138 of the Clinical Practice Guideline and p. 15 of the Quick Reference Guide for Clinicians, refer to treatment options. The Quick Reference Guide refers to a table in which the options and recommendations, including a recommendation of manipulation, are specifically set out. When the references contained in the AHCPR flowcharts are not ignored, it is clear that the AHCPR publications are a clear endorsement of manipulation as practiced by doctors of chiropractic where the Trigon clinical guideline is not.

4. The Trigon clinical guideline is inconsistent with the AHCPR Guidelines in many ways including the omission of any definition of manipulation which the AHCPR Guideline includes. Specifically, the Trigon clinical guideline refers only to manipulation. Manipulation is a generic term that encompasses a number of physical treatments from vigorous back massage to the type generally used by doctors of chiropractic, some osteopathic physicians, a relative handful of M.D.s and a relative handful of physical therapists. A study of members of The Rand Corporation estimated that chiropractors perform over 90% of spinal manipulations in the United States.

The AHCPR Clinical Practice Guideline, No. 95-0642, states beginning at p. 34:

> Spinal manipulation includes many different techniques. For this guideline, manipulation is defined as manual therapy in which loads are applied to the spine using short or long lever methods. The selected joint is moved to its end range of voluntary motion, followed by application of an impulse loading. The therapeutic objectives of manipulation

include symptomatic relief and functional improvement.

This definition refers to manipulation techniques learned by chiropractors during an extensive course of study. The AHCPR Quick Reference Guide for Clinicians, No. 95-0643, states at p. 12 that manipulation is "defined as manual loading of the spine using short or long leverage methods."

5. By omitting the AHCPR's definitions of manipulation, Trigon and its Managed Care Advisory Panel materially altered the recommendations of the AHCPR. That alteration created a Trigon guideline that did not recommend the manipulation that is provided primarily by doctors of chiropractic as did the AHCPR Guidelines. A point that became evident from the AHCPR guidelines was that manipulation was the only treatment approach that required a medical physician, in most instances, to make a referral of a patient with uncomplicated low back pain. The inevitable, and obviously intended, consequence of Trigon's and the Managed Care Advisory Panel's alteration of the AHCPR guideline, is to deprive patients of the benefit from spinal manipulation as practiced by doctors of chiropractic, and to deprive doctors of chiropractic of the opportunity to treat those patients.

Furthermore, the documents provided to me on the position of Trigon health Care in the treatment of neck and back pain are clearly in conflict with the recommendations from the most rigorous systematic reviews of the medical literature for the following reasons:

TRIGON HEALTH CARE GUIDELINES AND CRITERIA FOR THE TREATMENT OF BACK AND NECK PAIN.

The process used to develop the Trigon Health Care Guidelines

I have reviewed information concerning the qualifications and specialties of the members of the Trigon Provider Policy Committee and the Managed Care Advisory Panel as well as excerpts from minutes of meetings of the latter. I have reviewed sections of the depositions of Dr Grinnan and Dr Colley. The following appear to be reasonable conclusions from these documents.

1. It appears that the Managed Care Advisory Panel was responsible for the development and approval of treatment guidelines for Trigon Healthcare. The panel of physicians who developed and approved the Guidelines do not appear to include specialists whose training and primary case load is the treatment of back and neck pain or cervicogenic headaches. It appears that osteopathic physicians, chiropractors, and physical therapists who treat a large section of the population with back and neck pain and are the primary clinicians who utilize such procedures as spinal manipulation were not included in this panel. It is also not clear that there are any individuals in this panel with experience and training in epidemiology and clinical methodology, or who have experience in developing guidelines for conditions that are associated with the spine arid related disorders.

2. It is not evident that a systematic review of the medical and scientific literature was performed prior to developing the Trigon guidelines. There is a general consensus within the scientific medical community that systematic reviews of the scientific literature are a necessary and essential component in the development of evidence based treatment approaches and outcomes based recommendations. They are also only valid if they incorporate practitioners of all specialties that deal with the condition in question and that there be individuals with experience in methodology and epidemiology within the specialty to provide criteria to assess the scientific literature. This is necessary in order to ensure that the interpretation of this literature is consistent with clinical practice.

3. It is not evident from these records that the guidelines were developed using an established consensus methodology with active debate amongst the members of the panel. It is not evident that these guidelines were sent out to peer reviewers and consultants to ensure their accuracy. Furthermore, it is not evident that these guidelines were ever open to public review as is generally recommended.

<u>The Trigon Health Care Guidelines relative to other established Guidelines.</u>

I am in receipt of a report entitled "Managing Low Back Problems in Adults". This is described as a clinical practice guideline produced by Trigon Blue Cross/Blue Shield. There is a series of algorithms that look very similar to the AHCPR guidelines.

There is a marked discrepancy between the guidelines produced by the AHCPR and those

produced by Trigon in the table noted under "Treatment at Initial Visit". Under point 1, it recommends nonprescription analgesic medication, such as acetaminophen and NSAIDs. Under point 2, it suggests that a short trial of manipulation may be as effective as NSAIDs. This is clearly a deviation from the AHCPR guidelines, which suggested that manipulation could be used in place of medication or a shorter trial, if combined with NSAIDs. Under section 3, it recommends physical methods, but it is clear in the AHCPR guidelines that these treatment approaches are of very equivocal efficacy. The Trigon guidelines recommend heat or cold modalities, but in the AHCPR guidelines it suggested that these should only be used for home programs. The Trigon guidelines also recommend rest, whereas the AHCPR guidelines actually recommended against rest except in the presence of severe sciatica, and then for not more than two days. The Trigon guidelines also make no mention of manipulation as an option in patients with sciatica as noted in the AHCPR guidelines.

The Trigon guidelines made available to me provide no justification for this marked deviation in the recommended treatment approaches when compared to the AHCPR guidelines. Following the Trigon guidelines would lead to increasing costs of health care by justifying rest, which is known to prolong disability, and providing payments for heat and home modalities in an office, for which there is no justification. The failure to recommend manipulation as an initial treatment for acute low back pain would likely lead to increased symptomatology and prolonged disability.

Trigon policy on reimbursing manipulation.

I am in receipt of an office advisor document from Trigon dated July 1997. This document states, "It is Trigon's position that manipulation of more than two regions would rarely be evidence-based and/or medically necessary. Conclusive peer-reviewed evidence of manipulation efficacy is limited to lumbar spine procedures."

This is clearly in conflict with the current medical evidence and consensus guidelines, which suggest that manipulation is a reasonable approach to the treatment of neck pain, and there is at least as much or more evidence for the use of manipulation in neck pain than most other treatment approaches.

It is also in conflict with current scientific evidence on the different treatment approaches to cervicogenic headaches where there is again reasonable evidence in support of manipulation or at least more than other treatment approaches.

It is also in conflict with current epidemiologic evidence that it is common for patients to suffer from pain in multiple regions at the same time. Patients with low back pain commonly have neck or thoracic pain that would require treatment of multiple areas of the spine.

The minutes of the Managed Care Advisory Panel of October 25, 1995 include a discussion of the guidelines to be approved by this panel. Dr Colley emphasized that they were referral guidelines. Despite this policy it appears that this committee elected to utilize the words "may" and "should" instead of "may refer" or "should refer" in the

guidelines. A point that became evident from the AHCPR guidelines was that manipulation was the only treatment approach that required a family physician to make a referral of a patient with uncomplicated low back pain. The failure to emphasize the word "refer" is therefore most likely to impact practitioners of manipulation.

CONCLUSIONS

There is a strong need to develop and maintain guidelines for the treatment of back and neck pain which are based on an honest and systematic review of the medical literature in order to develop evidence based treatment approaches for back and neck pain.

When systematic review of the literature and consensus panels have been performed, the scientific literature clearly support a primary role for manipulation in the treatment of low back pain, and that the evidence for manipulation in the treatment of neck pain is equal to or better than almost all other treatment approaches.

The documents provided to me on the position of Trigon Health Care in the treatment of neck and back pain are clearly in conflict with the recommendations from the most rigorous systematic reviews of the medical literature.

I declare under penalty of perjury that the foregoing is true and correct.

/s/ Scott Haldeman
Scott Haldeman, M.D., Ph.D

SCOTT HALDEMA.N, M.D., Ph.D., F.R.C.P. (C)
A Professional Corporation
Consulting Neurology

Diplomate American Board of
Neurology and Psychiatry (Neurology}

1125 East 17th Street
Suite W-127
Santa Ana, California 92701

Telephone (714) 547-9822
FAX (714) 547-0443
E-Mail: HaldemamMD
@aol.com

July 27, 2002

Re: American Chiropractic Association, Inc., et al., vs. Trigon Health Care, Inc., et al. Civil Action: 1-00CV00113

EXPERT WITNESS REPORT

I have reviewed a series of documents referred to this office and have conducted independent research on the issues that appear to be germane to this case. The following is a report outlining my opinions in an attempt to answer questions that arise from these documents.

A copy of my Curriculum Vitae and bibliography is attached. The following are points from my curriculum vita that may be relevant to the questions posed by this case. Compensation for my time in the preparation of this report was a rate of $400 per hour.

QUALIFICATIONS

I am a graduate of Palmer College of Chiropractic in Davenport, Iowa, where I received a DC degree as valedictorian. I completed a Bachelor's and a Master's degree in Science at the University of Pretoria, South Africa. The Master's degree is in the field of neurophysiology, and

was achieved with honors. I received my Ph.D. at the University of British Columbia in Vancouver in the field of neurophysiology. I then completed a medical degree at the University of British Columbia, followed by an internship in internal medicine at Vancouver General Hospital. I completed a residency in neurology at the University of California at Irvine followed by a fellowship in electrodiagnosis at the Long Beach Veterans Administration Medical Center. I subsequently completed the training to become certified by the American Board of Psychiatry and Neurology and a diplomate of the American Board of Electroencephalography and Neurophysiology, the American Board of Clinical Neurophysiology and the American Board of Electrodiagnostic Medicine. I am a Fellow of the Royal College of Physicians of Canada and a Fellow of the College of Chiropractic Sciences in Canada.

EXPERIENCE

I currently hold a position of Clinical Professor in the Department of Neurology at the University of California at Irvine. I hold the position of Adjunct Professor in the Research Department at the Southern California University of Health Sciences. I have served as President of the North American Spine Society and on multiple committees of that society. I served for almost 10 years on the board of the American Back Society, and I currently hold the position of Chairman of the Research Council of the World Federation of Chiropractic. I am Editor in Chief of the *Journal of the Neuromusculoskeletal System* and section-editor of "The *Spine Journal*'. I am on the editorial boards of the *Journal of Manipulative and Physiological Therapeutics, Spine, the Journal of the Canadian Chiropractic Association,* and the *Journal of the Australian Chiropractic Association.*

I have had the privilege of serving on a number of consensus and guidelines expert panels that evaluated scientific evidence in favor of various treatment approaches.

I was on the panel on *Acute Low Back Pain in Adults* established by the U.S. Department of Health and Human Services Agency for Health Care Policy and Research. I chaired the panel to establish *Guidelines for Chiropractic Quality Assurance and Standards of Practice,* and I am an advisor to the guidelines committee of the North American Spine Society. I acted as facilitator of a subcommittee asked to assess the value of procedures used for the *Neurological Evaluation of Male Sexual Dysfunction* that presented a report for the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. I am currently President of the *Bone and Joint 2000-2070 Task Force on Neck Pain and its Associated Disorders.* Each one of these committees was established to look at the available scientific evidence in support of specific assessment or treatment procedures and perform a best evidence analysis for specific treatment approaches or for specific conditions.

SPECIFIC QUESTIONS

Following a review of the material before me I will attempt to complete the following tasks.

1. Briefly describe the history of chiropractic and its relationship to formal medical organizations and agencies.

2. Discuss guidelines, consensus conferences, and best evidence syntheses that have been performed by different agencies and individuals on various treatments for back pain, neck pain, and cervicogenic headaches. These three conditions account for 90% of all chiropractic treatments.

3. Review the guidelines established by Trigon Health Care, Inc., and compare those guideline's with the established best evidence synthesis and clinical guidelines established by other learned bodies.

BRIEF HISTORY OF CHIROPRACTIC

Definitions of chiropractic and spinal manipulation.

There are multiple definitions for spinal manipulation and for the practice of chiropractic that have been developed over the years.

For the purposes of this discussion, spinal manipulation will be considered to include all maneuvers where the hands are used to stretch, mobilize, or manipulate the spine and paraspinal tissues for the purposes of relieving spine-related pain and dysfunction. There are multiple techniques including various forms of mobilization, low force manipulations and high velocity, low amplitude adjustments. Spinal manipulation is offered as a treatment modality by chiropractors, osteopathic physicians and to a lesser extent by physical ~therapists and a small number of medical physicians.

The Agency for Health Care Policy and Research panel *on Acute Low back Pain in Adults* developed a very specific definition of spinal manipulation that is important in these proceedings as there appears to have been reliance on these guidelines by Trigon Healthcare Inc. The AHPR panel made the following statement: " Spinal manipulation includes many different techniques. For this guideline, manipulation is defined as manual therapy in which loads are applied to the spine using short and long lever methods. The selected joint is moved to its end range of voluntary motion, followed by application of an impulse loading. The therapeutic objectives of manipulation include symptomatic

relief and functional improvement."

For the purpose of this discussion, chiropractic will be defined as a health care profession as licensed in every state and province in the United States and Canada and in multiple countries throughout the world. The primary treating approach utilized by chiropractic includes various forms of spinal manipulation. It has been estimated that over 90% of all spinal manipulative treatments in the United States are performed by chiropractors. This, however, is not the only procedure offered by chiropractors. Many chiropractors utilize various physical modalities and rehabilitation procedures as well as the use of nutrition advice and counseling.

Medical associations and agencies are defined as associations or committees where the membership is either exclusively or primarily made up of medical physicians.

The practice of spinal manipulation:

Spinal manipulation is one of the oldest and most widely utilized procedures to be offered patients with spine-related pain symptomatology. References to spinal manipulation and the term subluxation can be traced back as far as Hippocrates and Galen. Manual and manipulative procedures have been depicted in the art and writings of most ancient cultures. Although manipulation has been part of orthopedic medical practice for centuries, most non-medical practitioners of spinal manipulation in the 19th century were "bonesetters" who learned their skills primarily through apprenticeship and observation.

At the end of the 19th century, Andrew Still and David Daniel Palmer formalized the practice of spinal manipulation into the professions of osteopathy and chiropractic. Osteopathy elected to assume an increasingly

allopathic practice model with a gradual reduction in interest and training in spinal manipulation. Although a significant number of osteopaths still practice spinal manipulation, the majority function as medical specialists and family practitioners.

Chiropractic, on the other hand, maintained its primary interest in spinal manipulation. There has been a progressive growth in the amount and quality of clinical and experimental research that has led to increasing acceptance of chiropractic and spinal manipulation.

This has resulted in a renewed interest in spinal manipulation by osteopathic physicians and incorporation of spinal manipulation into the practice of certain physiotherapists and a small cadre of medical physicians who have learned these techniques primarily in post-graduate education programs. It has been estimated that it takes approximately 1 year of full time training or 5 years of part-time training for a graduate medical physician or physical therapist to become efficient in the diagnostic and manual skills necessary to practice spinal manipulation competently.

A number of medical and chiropractic historians have reviewed the history of chiropractic over the last 20 years, and there is now an official Association for the History of Chiropractic with its own journal. It is not possible to review the events that have led to the growth of chiropractic over the past 100 years.

From the beginning chiropractors understood that professional self-regulation and independent legal status were crucial to survival. Although chiropractic as a profession originated in the United States, it took less than 10 years for chiropractors to emigrate and begin practicing in other countries. In 1923, the province of Alberta in

Canada became the first jurisdiction to license chiropractors outside the United States, and in 1939 the county of Zurich in Switzerland was the first to license the profession outside of North America. Today, chiropractors are licensed and regulated in many countries throughout the world, including a number of European countries, South Africa, Australia and New Zealand, and Hong Kong. The World Federation of Chiropractic now has membership associations from 74 different countries.

A brief review of the status of chiropractic and its evolution is outlined in a recent paper published by Meeker and Haldeman from the *Annals of Internal Medicine* (2002;136:216-227). This paper also discusses the role of chiropractic in health care, chiropractic training and licensure, and a description of diagnostic and treatment methods commonly employed by practicing chiropractors.

Relationship between medical physicians and chiropractors.

In the first few decades of chiropractic practice, there appeared to be relatively good relationships between individual medical physicians and chiropractors. Many medical physicians taught at chiropractic colleges. Following the Flexner report and the strengthening and control of the medical profession by the American Medical Association, it became unethical for medical physicians to interact with chiropractors. This led to isolation of chiropractors and chiropractic institutions. This greatly reduced the ability of chiropractors to access research resources and scientific institutions. In my opinion, this greatly decreased the evolution of chiropractic science and research from the 1960's to the early 1980's.

During my medical training I was informed by the registrar of the College of Physicians and Surgeons in Canada that it would be unethical to interact with a

chiropractor under any circumstances. I was also told by the professor and head of the Department of Neurology at the University of California at Irvine that "chiropractors should be wiped from the face of the earth". It was considered unethical for a chiropractor to be involved in medical associations and for medical physicians to accept referrals from chiropractors or refer patients to chiropractors.

This situation underwent significant changes in the 1970's and 1980's. The first formal interaction between chiropractors and medical physicians was the conference on "'*The Research Status of Spinal Manipulation*" sponsored by the National Institute of Neurological and Communicable Diseases and Stroke that issued a formal report in 1975. This conference, for the first time, incorporated speakers with qualifications in chiropractic, osteopathy, multiple medical specialties, and the basic sciences. It was this conference that stimulated research interest into spinal manipulation by chiropractors, osteopathic physicians, and medical practitioners who practiced this therapeutic approach.

During the 1970's, the last few states and provinces in North America passed legislation to license chiropractors. During this period there was also increased interest in chiropractic in other countries around the world. Various commissions and formalized committees were established to look into the role of chiropractic in health care. The most prominent and independent of these commissions was the Royal Commission bf Inquiry on Chiropractic in New Zealand, which issued a report in *1979.* They found that chiropractors had greater training in spinal mechanics and manual therapy than any of the other health care professions, and recommended that chiropractic be integrated into the health care system.

The factor that caused the greatest change in the relationship between chiropractors and medical physicians, and between medical institutions and chiropractic institutions was the resolution of the civil action entitled Chester Wilk, D.C., et al., vs. American Medical Association, et al. Following the change in medical ethics, there was a rapid growth in the interaction between chiropractors and medical physicians on multiple levels. There was a progressive increase in the rate of referral of patients by chiropractors to medical physicians and by medical physicians to chiropractors. A survey of family physicians and chiropractors in North Carolina found that two-thirds of medical physicians felt "moderately" or "very" informed about chiropractic, 65% admitted to referring patients to chiropractors, and 98% of chiropractors made routine referrals to physicians.

Chiropractic integration into multidisciplinary spine care centers has grown progressively over the past 10 years. Graduates of chiropractic colleges have been admitted and completed advanced degrees in medicine, epidemiology, and the basic sciences. These chiropractic scientists and chiropractic clinicians have used their scientific skills to further investigate the role of chiropractic in the community and the role of spinal manipulation in health care.

Mainline medical associations have opened their doors to chiropractors. Chiropractors now have their own division within the American Society of Public Health. Chiropractors have been on the board of the American Back Society for over 10 years, and participate in virtually all of their conferences. Chiropractors have been accepted as members in the International Society of the Lumbar Spine and the North American Spine Society. The North American Spine Society has a special interest group devoted to chiropractic. Chiropractic scientists commonly present papers at international meetings on biomechanics, public

health, spinal disorders, and epidemiology, as well as neurophysiology.

EVIDENCE BASED GUIDELINES

In the 1970's and 1980's, there was a marked proliferation of medical procedures used for the treating of patients with back and neck pain. There was a progressive increase in the cost of treating patients with back and neck pain, and it became evident that the scientific basis and evidence in favor of many of *these* treatments was inadequate. *Despite* marked increase in the cost of treating patients with back and neck pain there was an increase in the amount of disability due to these disorders. It became evident that it was necessary to systematically evaluate the scientific research and clinical trials and to develop guidelines outlining treatments most likely to benefit patients with back and neck pain.

The process of systematic reviews of the scientific literature and the development of guidelines is not unique to the treatment of spinal disorders. The basic principle of reviewing the literature and the development of evidence-based guidelines has replaced medical opinion as the most important and valid form of determining whether a treatment approach is reasonable and beneficial. The process of developing a best evidence synthesis and valid guidelines for treatment have undergone intensive study and is only considered valid if it has a number of well-defined components. These include the formation of a committee that includes representatives of all clinicians that have interest or knowledge of the topic and preferably with non-provider input. The process must be open and visible in its proceedings. It should include an in-depth analysis of the scientific literature outlining the method of determining the value of articles to be included for analysis. The guidelines should then be sent out for expert review and comment. A

public hearing to obtain input from interested parties not included in the review should follow this.

For the purpose of this presentation I will review three of the most commonly quoted guidelines that have been published for the treatment of back pain and neck pain with a critical review of cervicogenic headaches.

AHCPR Guidelines on Acute Low Back Problems in Adults.

This multidisciplinary panel comprised of health care professionals and consumer representatives who were brought together by the Agency for Health Care policy and Research to perform an evidence-based analysis of the research trials on all treatment approaches to acute low back pain in adults. I had the privilege of being a member of this panel that was chaired by Dr. Stanley Bigos, Professor of Orthopedic Surgery at the University of Washington in Seattle. This panel conducted a literature search for all articles published after 1984, and included articles, which may have been published prior to that date. Abstracts of over 10,000 papers were reviewed, and almost 4,000 articles were retrieved. Both assessment and treatment methods were studied, and an initial set of criteria for assessing the strength of evidence in favor of various treatment approaches was developed. Panel findings and recommendations for the primary assessment and treatment methods in use were developed by evaluating the research on the topic and by consensus where research was not available. This was an extraordinarily detailed and prolonged process, which continued over a period of almost two years. The results of this process were put out to peer review and subjected to public comment in an open forum. The results of this process are included in *Clinical-Practice Guidelines*, #14, "Acute Low Back Problems in Adults", published by the U.S. Department of Health and, Human Services. Algorithms were developed for the initial

assessment of acute low back pain symptoms, treatment of acute low back problems on the initial and follow-up visits, evaluation of the slow-to-recover patient, the surgical consideration for patients with persistent sciatica, and further care for acute low back problems.

Many of the recommendations were to rule out so-called "red flags" suggestive of severe or progressive pathology affecting the spine. It was recognized that only a very small percentage of patients have these red flags. In the absence of red flags, a series of recommendations was made. These included the provision of assurance that recovery is expected, recommendations for activities to avoid debilitation and reduce the risk of recurrence, support a return to work or required daily activities, and education that the patient can begin muscle-conditioning exercises after a few weeks.

A series of recommendations was given, which could be prescribed as comfort options based on a risk-benefit analysis and patient preference. The recommendations for symptom control are included in Table 2 of the *Quick Reference Guide for Clinicians.* Recommendations were for acetaminophen and NSAIDs, as well as manipulation in place of medication, or a short trial of manipulation combined with NSAIDs. No other treatment had sufficient quality of evidence to reach the level of recommendation. Treatment options included muscle relaxants and opioids for short periods, heat and cold modalities for home programs only, possibly shoe insoles, manipulation in place of medication, or combined with NSAIDs, if the patient has sciatica, with a few days of rest only in the presence of sciatica.

An outline of the levels of evidence in favor of different treatment approaches determined by this panel is noted in the table.

ACUTE LOW BACK PAIN IN ADULTS
Evidence based guidelines
(Bigo et al, AHCPR, 1994)
(A = strong research based evidence, B = moderate evidence, C = limited evidence, D = no information)

TREATMENT		LEVEL OF EVIDENCE
Patient education	Low back pain	Recommended (B)
Back school	Low back pain	Contradictory evidence (C)
Acetaminophen	Low back pain	Limited evidence (C)
NSAID	Low back pain	Moderate evidence (B)
Phenylbutazone	Low back pain	Not recommended (C)
Muscle relaxants	Low back Pain	Option, not combined (C)
Opioid analgesics	Low back pain	Limited time course (C)
Oral steroid	Low back Pain	Not recommended (C)
Colchicine	Low back pain	Not recommended (B)
Antidepressant medications	Low back pain	Not recommended (C)
Spinal manipulation	Low back pain	Strong evidence (B)
Spinal Manipulation	Radiculopathy	Option (C)
Physical agents and modalities	Low back pain	Not recommended (C)
TENS	Low back pain	Not recommended (C)
Shoe insoles and shoe lifts	Low back pain	With prolonged standing (C)
Lumbar Corsets and Back belts	Low back pain	No evidence (D)
Traction	Low back pain	Not recommended (B)
Biofeedback	Low back pain	Not recommended (C)

Trigger point and Ligamentous injections	Low back pain	Not recommended (C)
Facet joint injections	Low back pain	Not recommended (C)
Epidural injections	Low back pain	No evidence (D)
Epidural injections	Radicular pain	Option (C)
Acupuncture	Low back pain	No studies (D)
Activity modification	Low back pain	Limited evidence (D)
Bed rest	Low back pain	Not recommended (B)
Exercise, conditioning, aerobic	Low back pain	Limited evidence (C)

Quebec Task Force on Whiplash-Associated Disorders.

This task force was convened in Quebec, Canada for the purpose of developing a scientific monograph on the evaluation and treatment of patients who had neck pain and disorders associated with whiplash injuries. This scientific secretariat consisted of a multidisciplinary team dominated by epidemiologists and clinical methodologists with input from clinicians from all major health specialties that treat patients with neck pain. This task force developed a classification for whiplash-associated disorders and conducted a best evidence synthesis, reviewing all medical literature on the topic. This was published as a supplement to the journal *Spine (Vol* 20, #8S) and published on April 15, 1995.

After review of the scientific approaches, it was recommended that soft collars not be used, and that prescription drugs have a limited role in the management of whiplash-associated disorders and should be used sparingly. It was recommended that rest be seldom used. -

It was felt that manipulative treatment by a trained person for the relief of pain and facilitation of early mobility could be used in whiplash-associated disorders. Physiotherapy should emphasize early return to usual activity and the promotion of mobility. Surgery was felt to be rarely indicated, and only with progressive neurologic deficits. '

Swedish Council on Technology Assessment in Health Care.

A recently published textbook edited by Alf Nachemson and Egon Jonsson (Neck and Back Pain. The Scientific Evidence of Causes, Diagnosis, and Treatment. Lippincott, Williams and Wilkins, Philadelphia, 2000) presents the results of detailed evidence-based systematic review of the medical literature on the evaluation and treatment of patients with back and neck pain. This was done under the auspices of the Swedish council on technology assessment in health care and was published in 2000. It utilized the criteria of the Cochranc collaboration for evidence-based medicine, it was felt that evidence-based medicine is an approach to practicing medicine in which the clinician is aware of the evidence in support of his or her clinical practice and the strength of that evidence. They developed strength of evidence criteria for acute and subacute low back pain, chronic low back pain, acute and subacute neck pain, and chronic neck pain, as well as other conditions.

The final recommendations for treatment of acute low back pain recommended against the use of bed rest for simple back pain. It recommended that the patient stay as active as possible to continue normal daily activities. Paracetamol and NSAIDs at regular intervals for a fixed period could be offered, if required for pain relief. It was recommended that manipulative treatment within the first six weeks for patients who need additional help with pain relief or those who are failing to return to normal activities be considered. Patients should be advised to increase their physical activities gradually. It should be noted that the literature described moderate evidence that manipulation is more effective than a placebo treatment for short-term relief of acute low back pain, but because of inconsistent findings it was not possible to judge whether manipulation is more effective than other physical therapeutic applications. The risks were considered low, provided the treatment is carried out by a trained therapist or practitioner. It should be noted that there was no evidence available for the use of antidepressants, systemic steroids, or epidural injections in low back pain without nerve root pain, trigger point injections, facet joint injections, and many other commonly used medical treatment approaches. The levels of evidence are noted in the table.

ACUTE AND SUBACUTE LOW BACK PAIN
Levels of Evidence
A=strong, B--moderate, C=limited or contradictory,
D--no evidence
(Van Tulder MW and Waddell G. 2000)

TREATMENT	OUTCOME	COMPAR-ISON GROUP	LEVEL OF EVIDENCE
NSAIDs	Pain Relief	Placebo	Strong positive(A)
NSAIDs	RTW,	Placebo	Strong

	Natural history, Chronicity		negative(A)
Anti-depressants			No evidence(D)
Systemic steroids		Placebo	Not effective (C)
Epidural steroids	Back pain without root pain	Placebo	Limited Positive(C)
Epidural steroids	Back pain without root pain	Placebo	No evidence(D)
Trigger point injections			No evidence(D)
Facet injections			No evidence(D)
Bed rest	Multiple	Multiple	Strong negative(A)
Normal activity	Recovery disability	Analgesics and bed rest	Strong positive(A)
Specific exercises	Low back pain	Multiple	Strong negative(A)
Manual therapy	Pain Relief	Placebo	Moderate positive(B)
Manual therapy	Other therapies	Multiple	Inconsistent findings(C)
TENS	Low back pain		Conflicting (C)
Acupuncture			No evidence(D)

In the evaluation of conservative treatment for chronic low back pain, the recommendations for treatment were limited to providing information to the patient to avoid dependency on medical treatment, and the avoidance

of long-term drug treatment, with prescriptions only for fixed time periods. It was noted that, "The patient should be referred for manual therapy for pain relief." It was also recommended that patients be referred for exercise therapy to improve daily activity and that the intensity of exercise should be gradually increased. Multidisciplinary treatment aimed at functional restoration or behavioral management or pain management was felt to be reasonable. In this review of evidence, it was felt that there was strong evidence that manual therapy provided more effective short-term relief than placebo treatment. There was moderate evidence that manual therapy was more effective than usual care by a general practitioner, bed rest, analgesia, and massage for short-term pain relief. There was limited and conflicting evidence of any long-term effects. It was felt that there were various degrees of evidence for procedures like epidural steroid injections, electromyographic biofeedback, traction, and orthosis, as well as acupuncture.

The recommendations and the strength of evidence in support of each treatment approach are noted in the table.

CHRONIC LOW BACK PAIN
Levels of Evidence
A=strong, B--moderate, C=limited or contradictory,
D--no evidence
(Van Tulder MW, Goossens M, Waddell G,
Nachemson A. 2000)

TREATMENT	OUTCOME	COMPAR-ISON GROUP	LEVEL OF EVIDENCE
NSAIDs	Limited pain relief	Placebo	Limited evidence(C)
NSAIDs	Pain relief	Different NSAIDs	No difference(A)
Muscle	Pain	Placebo	Limited

relaxants	intensity		evidence(C)
Anti-depressants	Pain, depression	Placebo	Not effective(B)
Epidural steroids	Back pain with root pain	Placebo	Conflicting evidence(C)
Epidural steroids	Back pain without root pain	Placebo	Not effective(B)
Back School	Back pain	Multiple	Limited evidence(C)
Biofeedback	Back pain	Multiple	Not effective(B)
Traction	Back pain	Placebo	Strong negative(A)
Orthosis	Back pain	Non support	Limited evidence (C)
Manual therapy	Pain relief	Placebo	Strong positive(A)
Manual therapy	Pain relief	Multiple	Moderate positive(B)
Manual therapy	Long term relief	Multiple	Limited evidence(C)
TENS	Back pain		Inconsistent (C)
Acupuncture	Back pain	Placebo	Inconsistent findings(D)
Chemonu-cleolysis	Back pain	Placebo	Strong positive (A)
Discectomy	Sciatica (carefully selected		Moderate positive(B)
Discectomy	Sciatica		No evidence(D)
Lumbar fusion	Degenerative discs		No evidence(D)
Lumbar	Spondylo-		Limited

fusion	listhesis		evidence(C)

The chapter on acute and subacute neck pain provides a summary and conclusion, which states that staying active or continuing or returning to usual activities, reduces pain and decreases the consequences of acute neck pain. Painkillers and/or cervical collars should only be used for a limited period to enable patients to perform physical activity. There was moderate evidence that mobilization techniques when combined with other techniques and modalities help to improve range of motion and reduce pain faster than no treatment. There was also moderate evidence that active exercises are more effective than passive treatments, such as massage, heat, traction, and stretching. It was felt that when manual therapy is used in combination with other active treatment modalities there was moderate evidence that some patient groups may benefit from mobilization techniques as part of an activation program. The table describes the levels of evidence outlined in this chapter.

ACUTE AND SUBACUTE NECK PAIN
Levels of Evidence
A=strong, B--moderate, C=limited or contradictory,
D=no evidence
(Harms-Rindahl K and Nachemson A, 2000)

Vapo-coolant spray	Neck Pain	Placebo	Insufficient evidence(C)
Laser therapy	Neck pain	Placebo	Insufficient evidence(C)
Infrared therapy	Osteo-arthrosis	Placebo	No evidence(C)
TENS	Neck pain	Placebo	No effect(C)
Acu-puncture	Neck pain		No evidence(C)

Traction equipment	Neck pain	No traction	Limited negative(C)
Cervical Orthosis	Whiplash	No collar	No effect(C)
Supervised excercises	Neck pain	Brochure	Positive effect(C)
Manual therapy + Exercise	Neck pain	Passive treatment	Positive effect(C)
Patient education	Neck pain		Limited evidence(C)
Drug therapy	Neck pain		Insufficient evidence(C)
Surgery	Neck pain		No studies(D)

Critical review of the treatment of cervicogenic headaches

The notion that headaches may originate from disorders of the cervical spine and can be relieved by treatments directed at the neck is gaining recognition amongst headache clinicians but is often neglected in the spine literature. We performed a systematic literature review and critical evaluation of the literature using three computerized medical database (Medline, *CINAHL*, Mantis) that were searched for the terms "cervicogenic" and "headache". This was published in The *Spine Journal* (1, 31-46, 2001). After cross-referencing we retrieved 164 unique citations. Prevalence estimates range from 0.4 to 2.5% of the general population to 15-20% of chronic headache patients. CGH affects patients with a mean age of 42.9 years, have a 4:1 female disposition, and tend to be chronic.

CGH seems unresponsive to common headache medication. Sinail, uncontrolled case series have reported moderate success with surgery, spinal manipulation and injections. Although the research is not conclusive for any

treatment method commonly recommended for cervicogenic headaches there are more randomized controlled trials and case series support the use of cervical manipulation than any other form of treatment.

An independent review of the literature and Evidence Report on "Behavioral and Physical Treatments for Tension-related and Cervicogenic Headaches" was recently carried out by the Duke University Evidence Based Practice Center. They reached the conclusion that spinal manipulation was associated with significant improvement in headaches outcomes in trials involving neck pain and/or neck dysfunction and headaches. They felt that adverse effects are uncommon with manipulation

The relative evidence in favor of different treatment approaches to cervicogenic headaches.

CERVICOGEN-IC HEADACHES
Clinical evidence in support of
different treatment approaches
(Haldeman S and Dagenais S. The Spine Journal 2001)

TREAT-MENT	# UNCON-TROLLED CASE SERIES	COHORT STUDIES	RANDOM-IZED CON-TROLLED CLINICAL TRIALS
Surgery	9 (1-56 patients)	None	None
Radio-frequency rhizotomy	5 (7-24 patients)	None	None
Spinal manipulation	10 (1-332 patients)	1 positive	4 all positive
Injections	8 (1-180 patients)	2 both negative	1 positive

TENS	2 (20-60 patients)	None	None
Miscellaneous	4 (1-5 patients)	None	None

TRIGON HEALTH CARE GUIDELINES AND CRITERIA FOR THE TREATMENT OF BACK AND NECK PAIN.

The process used to develop the Trigon Health Care Guidelines

I have reviewed information concerning the qualifications, and specialties of the members of the Trigon Provider Policy Committee and the Managed Cart Advisory Panel as well as excerpts from minutes of meetings of the latter. I have reviewed sections of the depositions of Dr Grinnan and Dr Colley. The following appear to be reasonable conclusions from these documents.

1. It appears that the Managed Care Advisory Panel was responsible for the development and approval of treatment guidelines for Trigon Healthcare. The panel of physicians who developed and approved the Guidelines do not appear to include specialists whose training and primary case load is the treatment of back and neck pain or cervicogenic headaches. It appears that osteopathic physicians, chiropractors, and physical therapists who treat a large section of the population with back and neck pain and are the primary clinicians who utilize such procedures as spinal manipulation were not included in this panel. It is also not clear that there are any individuals in this panel with experience and training in epidemiology and clinical methodology, or who have experience in developing guidelines for conditions that are associated with the spine and related disorders.

2. It is not evident that a systematic review of the medical and scientific literature was performed prior to developing the Trigon guidelines. There is a general consensus within the scientific medical community that systematic reviews of the scientific literature are a necessary and essential component in the development of evidence based treatment approaches and outcomes based recommendations. They are also only valid if they incorporate practitioners of all specialties that deal with the condition in question and that there be individuals with experience in methodology and epidemiology within the specialty to provide criteria to assess the scientific literature. This is necessary in order to ensure that the interpretation of this literature is consistent with clinical practice.

3. It is not evident from these records that the guidelines were developed using an established consensus methodology with active debate amongst the members of the panel. It is not evident that these guidelines were sent out to peer reviewers and consultants to ensure their accuracy. Furthermore, it is not evident that these guidelines were ever open to public review as is generally recommended.

The Trigon Health Care Guidelines relative to other established Guidelines.

I am in receipt of a report entitled "Managing Low Back Problems in Adults". This is described as a clinical practice guideline produced by Trigon Blue Cross/Blue Shield. There is a series of algorithms that look very similar to the AHCPR guidelines.

There is a marked discrepancy between the guidelines produced by the AHCPR and those produced by Trigon in the table noted under "Treatment at Initial Visit". Under point 1, it recommends nonprescription analgesic

medication, such as acetaminophen and NSAIDs. Under point 2, it suggests that a short trial of manipulation may be as effective as NSAIDs. This is clearly a deviation from the AHCPR guidelines, which suggested that manipulation could be used in place of medication or a shorter trial, if combined with NSAIDs. Under section 3, it recommends physical methods or exercises, but it is clear in the AHCPR guidelines that these treatment approaches are of very equivocal efficacy. The Trigon guidelines recommend heat or cold modalities, but in the AHCPR guidelines it suggested that these should only be used for home programs. The Trigon guidelines also recommend rest, whereas the AHCPR guidelines actually recommended against rest except in the presence of severe sciatica, and then for not more than two days. The Trigon guidelines also make no mention of manipulation as an option in patients with sciatica as noted in the AHCPR guidelines.

The Trigon guidelines made available to me provide no justification for this marked deviation in the recommended treatment approaches when compared to the AHCPR guidelines. Following the Trigon guidelines would lead to increasing costs of heath care by justifying rest, which is "known to prolong disability, and providing payments for heat and home modalities in an office, for which there is no justification. The failure to recommend manipulation as an initial treatment for acute low back pain would likely lead to increased symptomatology and prolonged disability.

Trigon policy on reimbursing manipulation.

I am in receipt of an office advisor document from Trigon dated July 1997. This document states, "It is Trigon's position that manipulation of more than two regions would rarely be evidence-based and/or medically necessary. Conclusive peer-reviewed evidence of manipulation efficacy is limited to lumbar spine procedures."

This is clearly in conflict with the current medical evidence and consensus guidelines, which suggest that manipulation is a reasonable approach to the treatment of neck pain, and there is at least as much or more evidence for the use of manipulation in neck pain than most other treatment approaches

It is also in conflict with current scientific evidence on the different treatment approaches to cervicogenic headaches where there is again reasonable evidence in support of manipulation or at least more than other treatment approaches.

It is also in conflict with current epidemiologic evidence that it is common for patients to suffer from pain in multiple regions at the same time. Patients with low back pain commonly have neck or thoracic pain that would require treatment of multiple areas of the spine.

The minutes of the Managed Care Advisory Panel of October 25, 1995 include a discussion of the guidelines to be approved by this panel. Dr Colley emphasized that they were referral guidelines. Despite this policy it appears that this committee elected to utilize the words "may" and "should" instead of "may refer" or/'should refer" in the guidelines. A point that became evident from the AHCPR guidelines was that manipulation was the only' treatment approach that required a family physician to make a referral

of a patient with uncomplicated low back pain. The failure to emphasize the word "refer" is therefore most likely to impact practitioners of' manipulation.

CONCLUSIONS

There is a strong need to develop and maintain guidelines for the treatment of back and neck pain which are based on an honest and systematic review of the medical literature in order to develop evidence based treatment approaches for back and neck pain.

When systematic reviews of the literature and consensus panels have been performed, the scientific literature clearly supports a primary role for manipulation in the treatment of low back pain,, and that the evidence for manipulation in the treatment of neck pain is equal to or better than almost all other treatment approaches.

The documents provided to me on the position of Trigon Health Care in the treatment of neck and back pain are clearly in conflict with the recommendations from .the most rigorous systematic reviews of the medical literature.

Signed,

/s/Scott Haldeman
Scott Haldeman

Date: 26 July, 2002

ENCLOSED YOU WILL FIND THE LIST REQUESTED OF DEPOS AND TRIALS FROM THE YEARS 2000 THRU 2002, THE YEAR 1999 WAS IN OUR OLD COMPUTER

2001

SYSTEM AND IS UNAVAILABLE.

2000

1623 GIVENS VS. LUCY	TRIAL	#49
1659 KENDP, SCK, SANDRA	TRIAL	#6
1655 SJOLIE VS. JILL	DEPO	#49
1290 CLAVEL, DANIEL	DEPO	#8
1654 JUSTER VS. MARIAN	DEPO	#49
1771 FORMAN VS.DIDOMENICO	DEPO	#49
0956 WALDSCHMIDT, GUY	DEPO	#8
1727 BOWLES VS. PETERSON,DC	DEPO	#49
2016 AVALOS, JUAN	DEPO	#8
1100 GRONER, RACHAEL	DEPO	#8
0326 SHAVER, TOMMIE	TRIAL	#6
2081 GLYNN, LEONOR	TRIAL	#49
1304 ILES, PAMELA	DEPO	#8
1466 ROMERO VS. BERGMAN	TRIAL	#49
1972 SMITH VS. BOARDMAN	DEPO	#49
0624 WHITE, DEBORAH	DEPO	#5
2396 POTTER, KIMBERLY	DEPO	#8
2127 PLATEROS, SATURNINO	TRIAL	#49
1576 NADA, HUSSIEN	DEPO	#8
2146 PEACOR, MICHAEL	DEPO	#8
1013 OSBORNE, STOOT	DEPO	#49
2621 FLORES VS. CONCENTRA	DEPO	#49
2657 TORINO VS. QUARTZ	TRIAL	#49
2456 PRINCE VS. AUBREY	DEPO	#8

2001

0360 SONENSHINE, JILL	DEPO	#8
1934 HERNANDEZ, EDWARD	DEPO	#8
1677 BURCH, CHILISTINE	DEPO	#8
2563 CHANTAKASORN, WARAWAT	DEPO	#8
3119 EDWARDS VS. AMER. FARM INS	DEPO	#49
2720 LEAKY, SHARON	DEPO	#8
3180 BRENNER VS. ROSS	DEPO/TRIAL	#49
3253 BENJAMIN VS. KAPLAN	DEPO	#49
0514 WAMHOFF, MELVIN	DEPO	#8
2505 LEON, DEBRA	DEPO	#8
2642 ZEEMAN, TROY	DEPO	#8
2746 CORBIN VS. DOONE-EVANS	DEPO	#49
2873 CASTRO VS. COX	DEPO	#49
0108 AMBRIZ, JOSE	DEPO	#5
3614 NESBITT, THOMAS	DEPO	#6
3295 WASHINGTON, ROSITA	DEPO	#8
2284 CASTILLO, REYNA	DEPO	#8
2358 GARCIA, SUSAN	DEPO	#8
3356 BLACKMORE VS. POWELL	DEPO	#49
0275 DESOTO, NOEL	DEPO	#8
3366 PEREZ, FRANCISCO	DEPO	#8
3367 WEINFELD, HELEN	DEPO	#8

2002

0222 GEIST, LINDA	DEPO	#8
3442 LEWIS VS. LAWYER	TRIAL	#49
3153 PARKER VS. CURTIS	TRIAL	#49
2916 YTURRALDE, MICHAEL	DEPO	#8
3494 PADILLA, CHRIS	DEPO	#8
3690 GRANARD, DEBRA	TRIAL	#6
1972 SMITH VS. BOARDMAN	TRIAL	#49
2797 GARCIA/GAJADHAR, RACHAEL	DEPO	#6

0294 HANNA, DAVID	DEPO	#5
3435 GAtLIBAY, CARMEN	DEPO	#8
2358 GARCIA, SUSAN	DEPO	#8

CURRICULUM VITAE

Scott Haldeman

Mailing Address: 1125 E. 17th Street, Suite W-127
Santa Ana, California 92701
Telephone (714) 547-9822
Fax (714) 547-0443
E-mail: HaldemanMD@aol.com

Date of Birth: June 23, 1943

Marital Status: Married
Wife: Joan
Sons: Reeve and Keatly

Revised 9/01

Scott Haldeman, M.D.Page

BASIC QUALIFICATIONS

Degrees

D.C.	Palmer College of" Chiropractic, 1964
B.Sc.	University of Pretoria, 1968 (Physiology, Physics)
M.Sc.	University of Pretoria, 1970 (Neurophysiology)
Ph.D.	University of British Columbia 1973 (Neurophysiology)
M.D.	University of British Columbia 1976

Licensure Examinations

Iowa State Basic Science Board of Examiners, 1964
Canadian National Chiropractic Board of Examiners, 1970
Board of Directors of Chiropractic, Ontario Drugless Practitioners Act 1970
National Board of Chiropractic Examiners (United States), 1978
Medical Council of Canada Examinations (L.M.C.C.), 1976
Federation of Licensing Examination Boards (FLEX) - (United States), 1976
National Board of Medical Examiners (United States), 1976

Specialty Qualifications

FCCS - [Fellow of College of Chiropractic Sciences (Canada), 1975
FRCP(C) - Fellow of the Royal College of Physicians (Canada), 1981
Certified - American Board of Psychiatry & Neurology, 1982
Diplomate - American Board of Electroencephalography and Neurophysiology, 1981
Diplomate - American Board of Clinical Neurophysiology, Inc., 1983
Diplomat -- American Board of Electrodiagnostic Medicine, 1982

Academic Positions

Laboratory Assistant, University of Pretoria, 1968-1969
Student Academic Assistant, University of British Columbia, 1970-1971
Lecturer, Canadian Memorial Chiropractic College, 1970
Special Academic Staff, Chiropractic Sciences Division, Canadian Memorial Chiropractic College, 1976-1979

President, Neurology Department, University of California, Irvine, 1977-1980
Assistant Adjunct Professor, Department of Neurology, University of California, Irvine, 1980-1981
Attending Physician, Long Beach Veterans Administration Medical Center, 1980-1981
Assistant Clinical Professor, Department of Neurology, University of California, Irvine, 1984 to 1990
Adjunct Professor, Research Department, Southern California University of Health Sciences (formerly known as Los Angeles Chiropractic College), 1985 to Present
Associate Clinical Professor, Department of Neurology, University of California, Irvine, 1991 to 1998
Clinical Professor, Department of Neurology, University of California, Irvine, 1998 to Present "

UNIVERSITY AND COLLEGE HONORS

Valedictorian, Class of January 1962, Palmer College
Pi Tau Delta, Honor Society, Palmer College, 1964
Captain of the Rugby Team (college letters), Palmer College, 1963
President, Student International Chiropractors Association, Palmer College, 1963
International Chiropractors Association Student Achievement Award, 1963
President, Palmer College Flying Club, 1962
B.Sc. distinction in physiology
M.Sc. with honors
South African Medical Research Council Overseas Study Bursary, 1972
Louis Lipsy Toohill Scholarship in Rheumatology, University of British Columbia, 1972, 1974, and 1975
The Northwest Association of Physical Medicine and Rehabilitation Award, 1975

The Vancouver General Hospital, Department of Psychiatry Attending Staff Prize, 1975
The British Columbia Anesthetists Society Prize, 1976
Dr. A.M. Agnew Memorial Scholarship for Obstetrics, University of British Columbia, 1976
Dr. Peter H. Spohn Memorial Prize for Gynecology, University of British Columbia, 1976
Outstanding Achievement by Volunteer Faculty, University of California, Department of Neurology, 1999

CHIROPRACTIC HONORS

Certificate of Merit, South African Chiropractors Association, 1967
Chiropractor of the Year, South African Chiropractors Association, 1968
Palmer College Alumni Award, 1968
Research Fellowship, Foundation of Chiropractic Education and Research, 1975
Doctor of Science degree (honorary), Western States Chiropractic College, 1981
Researcher of the Year Award, American Chiropractic Association, 1990
Chiropractor of the Year, Dynamic Chiropractic, 1991

CLINICAL EXPERIENCE

Private Practice, Chiropractic, 1964-1977
Internship, Medicine, June 1976-1977
Resident, Neurology, July 1977-June 1980
Fellow, Electrodiagnosis, Veterans Administration Medical Center, Long Beach, California, September 1980-August 1981
Private Practice, Neurology, January 1981-Present

HOSPITAL AFFILIATIONS

St. Joseph Hospital, Orange, California
University of California, Irvine Medical Center, Orange, California

PROFESSIONAL ORGANIZATIONS

American Academy of Neurology, 1977-Present
Orange County Medical Society, 1982-Present
California Medical Association, 1984-Present
American Medical Association, 1982-Present
International Society for the Study of the Lumbar Spine, 1979-Present
American Back Society, 1984-1994
North American Spine Society, 1984-Present
North American Academy of Manipulative Medicine, 1977-1995
Currently American Academy of Orthopedic Medicine
American Chiropractic Association, 1976 -Present
International Chiropractic Association 1971-1990
Federation International de Medecine Manuell, 1981-1993
National Back Research Foundation, 1981-1985
American Medical EEG Society, 1982-1994
Orange County Neurological Society, 1982-Present
American Association of Electrodiagnosis and Electromyography - Currently American Academy of Electrodiagnostic Medicine, 1982-Present
North American Cervicogenic Headache Society, 1996-present

Chiropractic Committees and Positions

Research Consultant, Canadian Chiropractic Association, 1973-1979

Research Consultant, American Chiropractic Association, 1975-I979
Research Consultant International Chiropractic Association, 1973-1982
Consultant, Foundation for the Advancement of Chiropractic Research, 1979
Consultant, Foundation for Chiropractic Education and Research, 1979
Executive Member, South African Chiropractors Association, 1965-1969
Founding Committee, South A/Rican Chiropractic research Foundation 1968-1969
Canadian Chiropractic Association Committee for a definition of Chiropractic, 1970
British Columbia Chiropractic Association, Public Relations Committee, 1971-1972
British Columbia Chiropractic Association, Committee to Investigate the Establishment of a Faculty of Chiropractic, 1974
"ICA Review," Technical Paper Review Committee, 1978-1979
American Chiropractic Association, Council of Neurology, 1974-1977
Canadian Chiropractic Association, Convention Organizing Committee, 1976
International Chiropractors Association, Conference Committee, 1979
Guidelines for Chiropractic Quality Assurance and Standards of Practice, Chairman, 1990-1992
World Federation of Chiropractic Research Council Chairman, 1990-present
National Workshop to Develop the Chiropractic Research Agenda Member of Planning Committee and participant, 1995-1996
College of Chiropractors Faculty of Neurology, Hon. President, 1999

Medical Committees and Position

Vancouver General Hospital Back Pain Special Interest Group, 1976-1977
North American Academy of Manipulative Medicine

- Counselor, 1975-1979
- Vice-President 1980
- President-Elect 1981
- President 1983
- Resident 3rd Vice-President 1986-1988

University of California, Irvine, Manipulation Research Committee, 1978
International Society for the Study of the Lumbar Spine

- Membership Committee 1980-1982
- Chairman 1982
- Executive Committee 1992-1994

Physical Medicine Research Foundation, International Multidisciplinary Board, National Back Foundation, Advisory Council, 1984
California Medical Association, Committee on Health Care, 1984-1986
American Back Society, Board of Directors, 1985-1994
North American Spine Society

- Executive Council 1984-1986
- Vice-President and President-Elect 1987
- President 1988-1989
- Parliamentarian 1989

Public Relations Committee 1991
Long Range Planning Committee 1992
Membership Committee 1992-present
Practice Guidelines 1996
Guidelines Committee 1997
Advisory Panel 1997
NASSNews Sub-Committee/Editorial Board 1997
Research Fund Management Committee 1999
Member, Combined Task Force of the North American

Spine Society, American Society of Spine Radiology, and American Society of Nueroradiology - Nomenclature and Classification of Lumbar Disc Pathology. Published in Spine, Vol. 26, No. 5, 2001

Orange County Neurological Society, President 1988-1989

American Academy of Neurology

- Liaison with North American Spine Society, 1989-1995
- Facilitator - Assessment: The Neurological Evaluation of Male Sexual Dysfunction. Report of the Therapeutics and Technology Assessment Subcommittee, 1993-1995
- Course Director: Recent changes in the treatment of back pain. AAN Annual Meeting, 1993, 1994, 1995

American Academy of Orthopedic Surgery

- Orthopedic Research Society. Panelist, Occupational Medical Science Study Group, 1995
- New Horizons in Low Back Pain. Workshop participant, 1995

Value Health Sciences. Panel member, "Laminectomy and Spinal Fusion," September 1992

American Board of Independent Medical Examiners. Examination Committee, 1995-1996

North American Cervicogenic Headache Society. Member, Scientific Board, 1996

Government Committees and Positions

National Institute of Neurological Diseases and Stroke Committee to Establish a Workshop on the Research Status of Spinal Manipulative Therapy, 1974-1975

State of California, Division of Industrial Accidents, Low Back Disability Schedule Committee, 1984-1987

State of California, Division of Industrial Accidents, Medical Bureau. Committee on Chiropractic Standards, 1985-1986

U.S. Department of Heath and Human Services, Agency for Heath Care Policy and Research. Panel member - "Clinical

Practice Guidelines on Acute Low Back Problems in Adults," 1994
Member of Spine Specialist Panel, Commission on Peace Officer Standards and Training, State of California, 1992
Independent Medical Examiner, State of California, Department of Industrial Relations, 1983 to Present
Qualified Medical Examiner, State of California, Department of Industrial Relations, 1991 - present
Consultant, Birch & Davis, U.S. Department of Defense, Chiropractic Demonstration Project, 1995 - present
Agency for Health Care Policy and Research. Peer Reviewer, "Headache Evident Report Project," 1997

Editorial Boards

Journal of Manipulative and Physiological Therapeutics, Editorial Board, 1979 - Present
North American Academy of Manipulative Medicine Newsletter, Editor, 1980-1982
Australian Chiropractic Association, Editorial Board, 1983 - Present
Journal of the Canadian Chiropractic Association, Editorial Board, 1985 - Present
International Chiropractic Association, Editorial Advisory Board, 1983
National Back Foundation, Advisory Council, 1984
Manual Medicine, Editorial Board, 1984-1992
Neuro-Orthopedics. Editorial Board, 1986-1995
Spine, Associate Editor, 1988-Present
The Back Letter, Editorial Board, 1992-1994
Rodale Press, Book Division Board of Advisors, 1992-Present
Spine Letter, Editorial Board, 1994-Present
Journal of the Neuromusculoskeletal System, Editor in Chief, 1992-Present
Injury Data Corporation Newsletter, Founding Medical Advisory Board, 1996

INVITED LECTURES

1985

Lumbar Spine Seminar, sponsored by St. Joseph Hospital, Orange, California, February 9. "'Manipulative Therapy"; "Flexion vs. Extension Exercises."

Back Pain Symposium, sponsored by British Columbia Chiropractic Association, March 15 - 16. "Spinal Pain Syndrome"; "An Overview of Trials of Manipulation"; "Neuropsychological Models"; "Concluding Remarks."

Western States Chiropractic College's Homecoming '85, sponsored by Western States Chiropractic College, Portland, Oregon~ May 3 - 5. "Cervical Spine Pain Syndrome - Diagnosis and Treatment."

San Bernandino County Medical Center Meeting, sponsored by Syntex Speaker's Bureau San Bernadino, California, May 30. "Low Back Pain."

Fourth International Conference on Low Back Pain, sponsored by Canadian Memorial College, Toronto, Canada, June 1 - 2. "Clinical Evaluation of Neurovisceral Function."

Joint Orange County Workers' Compensation Carriers and Defense Counsel Association, sponsored by JOCWCCDCA, Santa Ana California June 27. Guest speaker. "Low Back Pain: A Real Pathology or a Donor's Bonanza."

Second Annual Meeting, sponsored by North American Lumbar Spine Association Laguna Niguel, California July 24 - 27. Session Chairman on Clinical Neurophysiology. "The Comprehensive Evaluation of Lumbar Neurological Lesions

Utilizing EMG, H-Reflexes, F-Responses, SEPs, BCK, Cystometry, and Colonometry."

Summer Convention and Educational Symposium, sponsored by Washington Chiropractors Association, Coeur d' Alene, Idaho, August 16 - 18. "Neurology and Chiropractic."

Seventh Annual Challenge of the Lumbar Spine '85, sponsored by Abbott Northwestern Hospital and its Rehabilitation Division, the Sister Kenny Institute, Minneapolis, Minnesota, September 19 - 21. "Thermography for Musculoskeletal Disorders: Real or Pip-off?" Moderator on low back pain.

Pain and Ethics in the Emergency Department, sponsored by Cedars-Sinai Medical Center, Department of Emergency Medicine, Los Angeles, California, September 27. "Low Back Pain."

Symposium on Back Pain, sponsored by the American Back Society, San Francisco, California October 4. "'Conservative Treatment of Spinal Pain"; Electrodiagnostic Evaluation of Spinal Disorders"; "Spinal Manipulation."

First International Congress, Back Pain: Current Concepts and Recent Advances, Vienna, Australia November 3 - 8. "Clinical Neuroanatomy of the Spine"; "What are the Objectives of Conservative Treatment?"

1986

Ninth Annual Conference on Evoked Potential and Advances in Electroencephalography, sponsored by UCI Department of Neurology, L-vine, California, January 24 - 26. "Pudendal evoked Responses - Techniques and Applications."

Symposium on Back Pain, sponsored by the American Back Society, Anaheim California, May 9 - 10. "Manipulation of the Spine."

Seventh Annual AOA International Symposium: Frontiers in Low Back Pain, sponsored by American Orthopedic Association Chicago, Illinois, August 17 - 22. "Electrodiagnosis of Spinal Neurologic Lesions"; "Spinal Manipulative Treatment."

Annual Conference 1986, sponsored by Association for Holistic Health San Francisco, California, August 29 - September Modern Treatment of Back Disorders."

Low Back Pain: A Multidisciplinary Approach, sponsored by Workers' Compensation Board of British Columbia, Vancouver, B.C., October 2 - 4. "The Circuitry of Pain"; "The Role of Manipulation"; "EMGs: Are They Helpful?"

Occupational Low Back Pain Course, sponsored by University of Utah, Snowbird, Utah, October 6 - 8. "Electrodiagnostic Studies"; "Manipulation."

The Challenge of the Lumbar Spine '86, sponsored by St. Mary's Hospital and Medical Center, St. Mary's Spine Center, San Francisco, California, November 6 - 9. "Problems facing the Spine Specialist as Viewed by the Neurologist"; "Over-treatment as Viewed by the Neurologist"; Moderator on topic: Electrodiagnosis and Thermography. Chairman of Thermography Panel.

Fall Symposium on Back Pain, sponsored by American Back Society, San Francisco, California, December 4 - 6. "'Spinal Manipulative Therapy and Sports Medicine."

1987

Spring Symposium on Back Pain sponsored by the American Back Society, Anaheim, California, April 29 - May 2. Position: Member of the Board of Directors. "Electrodiagnostic Studies: Indications and Techniques"; "Short-term Trial of Chiropractic Adjustments for the Relief of Chronic Low Back *Pain*."

North American Spine Society, Second Annual Meeting, sponsored by NASS, Banff Alberta, Canada, June 25 - 28. "'The Correlation Between CT Scanning, Electrodiagnostic Studies, and Clinical Findings in Workers' Compensation Patients with Back and Leg Pain."

Bisbane Spinal Study Group, Brisbane, Australia, August 21 - 23.

Role of Manipulation in Sports Medicine, sponsored by North American Academy of Manipulative Medicine, Las Vegas, Nevada, October 28 - 31. "'The Role of Manipulation in Sports Medicine."

1988

Industrial Musculoskeletal Health: Sports Medicine for Working People, sponsored by Division of Orthopedic Surgery, Southwestern Medical School, the University of Text, Southwestern Medical Center, Dallas, Texas, September 15 - 17. "Selecting Among Manipulation and Other *Modalities*"; "Office Management of Disabled Workers"; "Workman's Compensation: The California System of Evaluating Permanent and Partial Impairment."

Low Back Pain - A Changing Paradigm, sponsored by Physical Medical Research Foundation, Ontario, Canada, September 30 - October 2. "The Objectives of Conservative Management of Low Back Pain."

Occupational Low Back Pain Conference, sponsored by Rehabilitation Engineering Center, Department of Orthopedics and Rehabilitation, University of Vermont College of Medicine, Hilton Head, South Carolina, October 16 - 19. "Disability Ratings"; "Electrodiagnostic Studies"; Manipulation: Theory, Practice, and Utilization."

The Challenge of the Lumbar Spine '88, sponsored by The Arthritis Foundation, San Antonio, Texas, November 9 - 13. "'Non-specific Low Back Pain Syndrome - What is it? Why does it "happen?"

Fall Symposium on Back Pain, sponsored by American Back Society, San Francisco, California, December I - 3. "Clinical Spinal Neural Anatomy and Neurophysiology."

Second International Interdisciplinary Chiropractic Seminar, sponsored by Sociedad Cientrifico Quiropractica de Mexico, Mexico City, Mexico, February 16 - 19.

The 118th Annual Session and Western Scientific Assembly, sponsored by California Medical Association Anaheim, California, March 3 - 8. "Conservative Treatment: Objectives, Choices, Results."

Invited Lecture Series, sponsored by Palmer College of Chiropractic Graduate School, UCI, April 1 ~. "Current and Future Clinical Research Status of the Chiropractic Adjustment."

Spring Symposium on Back Pain, sponsored by American Back Society, Cambridge, Massachusetts, April 13 - 15. "Differentiation of Acute and Chronic Back Pain."

The 9th Annual Conference on Evoked Potentials, sponsored by the American Society for Clinical Evoked Potentials, San Francisco, California, May 3 - 6. "Evaluation of Bowel, Bladder, and Sexual Disturbances by Electrophysiologic Methods"; "Evoked Responses in Clinical Neuro-Urology"; "Pudendal Nerve Evoked Spinal, Cortical, and Bulbocavemosus Reflex Responses: Methods and Applications"; "The Neurovisceral and Electrodiagnosis Evaluation of Patients with Thoracic Spinal Cord Injury."

The First Annual Multidisciplinary Symposium - Cervical Spine '89, sponsored by New York Chiropractic College, New York, September 12- 16. Position: Master of Ceremonies. "Defining Spinal Manipulation"; "Complications of Cervical Manipulation."

XVIIth ILAR Congress of Rheumatology, sponsored by ILAR, Rio de Janeiro, Brazil September 17 - 23. "Physiotherapy and Manipulation in the Management of Back Pain."

Congresso Intenacional Sobre Coluna Vertebral, sponsored by Centro Brasilero de Estudos de Coluna Vertebral Sao Paolo, September 24 - 26. "Physiotherapy and Manipulation in the Management of "Back Pain"; "Defining Spinal Manipulation."

Tenth Annual National Occupational Low Back Pain Conference, sponsored by UCI Department of Neurology, Long Beach, California, October 18 - 21. "Acute versus Chronic Pain"; "Electrodiagnosis"; Manipulation - Indications and Limitation"; "Rating Systems - Principles and Problems."

Perspectives on Pain - Low Back Pain: Mechanisms and Management. Sponsored by Challenge of' the Lumbar Spine, San Francisco, California, November 2 - 5. Differential Diagnosis of Low Back Pain"; "Social and Legal Aspects."

Fall Symposium on Back Pain, sponsored by the American Back Society, Las Vega, Nevada, November 30 - December 2. "Complications of Cervical Spine Manipulation."

1990

Thirteenth Annual Evoked Potential and Electrodiagnostic Workshop, sponsored by UCI Department of' Neurology, Irvine, California, February 2 - 4. "Bladder and Genital SEPs."

Advanced Seminar, sponsored by Motion Palpation Institute, Maui, Hawaii, February 25 - March 3. "Malpractice Suits: reducing Frequency and Increasing Dependability"; "Research: Beneficial Response to Chiropractic"; "Relationship: Spinal Pathology, Patient Symptoms"; "Conservative Treatment and Approaches."

Back Pain in the Nineties: New Solutions to Old Problems, sponsored by University of Colorado Health Sciences Center, Denver, Colorado, Ms, oh 16 - 17. "Scope of Back P~ Problems."

Primary Care and Diagnosis for the Chiropractic Profession sponsored by Orange County Chiropractic Association, Santa Ana, California, April 1 Position Guest Speaker

Bright Horizons for Chiropractic, sponsored by the American Chiropractic Association, Anchorage, Alaska, June 6-9. "Chiropractic Philosophy: The Relevance in the 90s."

Homecoming VI, "A Decade of Growth & Vision,' sponsored by Palmer College of Chiropractic West, San Jose, California, October 18-21. "Failure of the Medical Pathology Model to Explain Back Pain.:

Eleventh Annual Low Back Pan Conference, sponsored by University of Michigan Center for Occupational Health and Safety Engineering, Ann Abor, Michigan, October 29-30. "Acute and Chronic Low Back Pain"; "Impairment Rating Systems."

The Many Faces of Pain conference sponsored by the North American Academy of Musculoskeletal Medicine, Tucson, Arizona, November 8-10. "The Failure of the Pathological Model to Explain the Presence of Back Pain"; "Advanced Seminar"; "Assessment of Craniocervical Dysfunction and Risk Factors for Chronic Pain: A Neurologist's View of the Role of Manual Medicine."

Fall Symposium on Back Pain, sponsored by the Americaa Back Society, San Francisco, California, December 6 - 9. Course Chairman/Moderator.

1991

Neurology and Neurosurgery Review Courses, sponsored by Osler Institute, Los Angeles, California, January 6 - 12. "Electrodiagnosis of Spinal Disorders"; "Low Back Pain." -

Fifty-eighth Annual Meeting, American Academy of Orthopedic Surgeons, Anaheim, California March 7 - 12. "Indications and Results of' Manipulative Treatment for Low Back Pain."

Medical Coordination of Workers' Compensation Claims Class, sponsored by Reliance Insurance Company, March 25. "Diagnostic testing and pain management."

Spring Symposium on Back Pain, sponsored by the American Back Society, Toronto, Canada,
May 1 - 5. Course Director, Clinic Faculty. "The Clinical Evaluation of Patients with Neurovisceral Disorders."

World Chiropractic Congress 1991, sponsored by World Federation of Chiropractic, Toronto, Canada, May 4 - 5. Course chairman. "The Evolution and Importance of Spinal and Chiropractic research."

Back Pain Current Concepts and Advances, 4th International Congress, sponsored by International Back Pain Society, Sydney, Australia, June 6 - 9. "The Neurophysiological Bas{s of Back Pain"; "Neurophysiological Assessment'; "Manipulation."

Occupational Spinal Disorders: Prevention, Diagnosis & Treatment, sponsored by University of Vermont, College of Medicine, Chicago, Illinois, September 22 - 24. "Pain"; "Conservative Treatment Options"; "California Approaches to Disability Evaluation."

Fourth International Symposium, Physical Medicine Research Foundation, Toronto, Canada, September 27 - 29 Manipulation"; Failure of the Pathology Model to Predict Back Pain."

Report Writing Seminar, sponsored by Workers' Compensation Advisor and Stress Management Advisor, Los Angeles, California, October 19. "Apportionment in Physical Disabilities."

Fall Symposium on Back Pain, sponsored by American Back Society, San Francisco, California, December 11 - 15. "Current Status of Functional and Palpatory Diagnosis."

1992

Occupational Ergonomics: Work Evaluation and Prevention of Upper Limb and Back Disorders, sponsored by Workers' Evaluation and Rehabilitation Center Department of Occupational Therapy, Loma Linda University, San Diego, California, February 24. "Failure of the Pathology Model to Explain Low Back Pain'; "Conservative Management of Low Back Pain."

Adjustment and Manipulation for Spinal Pain sponsored by British Columbia College of Chiropractic, Vancouver, B.C., February 27 - March 1. "Failure of the Pathology Model ~o Explain Spinal Pain"; "Practical Applications of Spinal Pain Physiology"; "Acute vs. Chronic Pain."

Annual Session and Western Scientific Assembly, sponsored by California Medical Association~ Anaheim, California, March 13 - 18. "The Role of Chiropractic Manipulation"; "The Role of Electrical Studies in Evaluation of Surgical Candidates."

Clinical Seminars in Sports Medicine, sponsored by Tarzana Regional Medical Center, Orthopedic Consultants Medical Group, and Cummings and G-Gillette Physical Therapy, Northridge, California, March 21. "Evaluation of Indications and Effectiveness of Spinal Manipulation."

National Football League Physicians Society Conference, sponsored by National Football League Physicians Society, San Francisco, California, April 3 - 5. "'The Rote of Manipulation and Mobilization."

Canadian Chiropractic Association Convention '92, Regina, Saskatchewan, May 27 - 3 I. "Neurologic Assessment"; "Looking to the Twenty-First Century."

Fifth International Conference, sponsored by International Federation of Orthopaedic Manipulative Therapists, Vail, Colorado, June I - 5. "Chiropractic Research - Past and Present"; "Chiropractic - Let's Cooperate."

Seventh Annual Meeting, sponsored by North American Spine Society, Boston, Massachusetts, July 9 - 11. Moderator of session on Neurophysiology and Electrodiagnostics.

Occupational Spinal Disorders: Primary, Secondary, and Tertiary Care and Prevention, sponsored by Pride Research Foundation, University of Vermont, Dallas, Texas, October 1 - 3. Moderator on topic of Basic Science: "Classification and Diagnostic Tests for Back Pain"; "Structural Diagnostic Tests"; "Physics/Therapy and Chiropractic Approaches to Secondary Prevention"; "Alternative Systems for Disability Evaluation."

Palmer College Graduating Class Commencement Address, Davenport, Iowa, October Position: Keynote Speaker.

The Industrial Back, sponsored by the American Back Society, San Francisco, California, December 9-13. Moderator: "Taking an Effective Work Injury History."

1993

Occupational Ergonomics, February 22, San Diego, California Failure of Pathology to Explain Low Back Pain" and "Conservative Management of' Low Back Pain."

Los Angeles College of Chiropractic 6th Annual Interdisciplinary Symposium - "Neurobiological Mechanisms of Spinal Manipulation." March 6, Whittier, California.

Orange County Chiropractic Society, March 9, Costa Mesa, California. "The Electrodiagnostic Evaluation of Spinal Disorders."

Chang Zheng Hospital, The Second Military Medical University of China, Shanghai Tang Du Hospital, The fourth Military Medical University of China, Xian The Third Military Hospital, Beijing Medical University, Beijing, China. "Back Pain."

American Academy of Neurology Annual Meeting, April 25, New York City. Course Chairman. Recent Advances on the Evaluation and Treatment of Back Pain."

San Francisco Spine Institute, April 30, San Francisco, California. '~NASS Nomenclature/Chiropractic Language: Lets Call It What It Is" and Electrodiagnostics: When Are EMG, NCV, SSEP Useful?"

Occupational Spinal Disorders, October 4 - 5, Pittsburgh% Pennsylvania. "The Anatomy and Physiology of Back Pain: What Do We know?"

South Africa International Chiropractic Congress, October 10 - 15, Sun City,. South Africa- "'Failure of the Pathology Model to Explain Back Pain"; "Research Supporting the Efficacy of Chiropractic Manipulative Procedures."

1994

University of California, Irvine, February 11 - 13, Newport Beach, California. Course Chairman. "The Neurologist and Back Pain: Musculoskeletal Diagnosis and Management."

Occupational Ergonomics, February 23, San Diego, California- "Failure of Pathology to Explain Low Back Pain" and "Conservative Management of Low Back Pain."

California Medical Association, March 18, March 20, Anaheim, California. Course on Practical Neurology: The Old, and The New and Promising. "Multiple Views of Pain Management."

American Academy of Neurology, May 6, Washington, D.C. Course Chairman. "Recent Advances in the Evaluation and Treatment of Back Pain."

Occupational Spinal Disorders, September 25 - 26, Atlanta, Georgia. "Spinal Manipulation: The Legitimization of a Treatment Procedure."

American Back Society, November 30 - December 2, Los Angeles, California. "Guidelines for Managed Care of Low Back Pain" and "Myths Concerning Strokes Following Cervical Manipulation."

1995

Council on Chiropractic Education Convocation, New Orleans, Louisiana January 27. "The Role of Chiropractic in an Integrated Health Care System."

Occupational Ergonomics: Work Evaluation and Prevention of Upper Limb and Back Disorders, sponsored by the University of Michigan, American Industrial Hygiene Association, San Diego Local Section, State Compensation Insurance Fund of California; San Diego, California, February 20 - 23. "Failure of the Pathology Model to Explain Low Back Pain"; "Conservative Management of Low Back Pain."

Netherlands Manual Therapy Association Conference, sponsored by NV[illegible], conducted via video at View Tech, Inc., Irvine, Califo[illegible]a, April 28. Topic: Lumbar and cervical spine.

Forty-seventh Annual Meeting, American Academy of Neurology, Seattle, May 6 - 13. Course Director. Topic: Recent Advances in the Treatment of Back Pain.

Texas Medical. Association Spring Program, sponsored by University of Texas MID Anderson Cancer Center, Dallas, Texas, May 11 - 20. "Spinal Manipulation for Low Back Pain."

International Workers' Compensation Foundation Forum VII, sponsored by IABC, Newport Beach, California, May 23. "The Legitimization of a Treatment Procedure."

International Society for the Study of the Lumbar Spine 22nd Annual Meeting, Helsinki, Finland, June l8 - 22. "The correlation 0f palpable muscle spasm, pain, and activity scores and cerebral potentials evoked by the magnetic stimulation of paraspinal musclea." Session Chairman.

Chiropractic Centennial Foundation Convention, sponsored by World Federation of Chiropractic, Washington, D.C., July 5 - 7. Co-Chair, Academic Program. "One Hundred Years of Chiropractic Research."

Sixteenth Annual Occupational Spinal Disorders Conference, sponsored by Canadian Back Institute Toronto, Canada, September 10 - 11. 'X-low to Prescribe Optimal Manipulative Therapy"; "X-low to Handle the Legal Implications of Aggressive Therapy."

Chiropractic Centennial Foundation Celebration, sponsored by World Federation of Chiropractic, Davenport, Iowa, September 14 - 16. "One Hundred years of Chiropractic Research." Workshop on spinal neurophysiology and somatovisceral reflexes.

Chiropractic Centennial Celebration, sponsored by Doctors of Chiropractic Liaison Council, Tokyo, Japan, November 18 - 19. "One Hundred Years of Chiropractic Research"; "Neurophysiological theories on which chiropractic in based"; "The clinical research which has established chiropractic as an accepted health care profession."

1996

Defending the Personal Injury Lawsuit sponsored by State Farm Mutual Insurance Company, Los Angeles, California, February 24. "Spinal Manipulation and Chiropractic Treatment for Spinal Pain Syndromes."

Occupational Ergonomics: Work Evaluation and Prevention of Upper Limb and Back Disorders, sponsored by University of Michigan and State Compensation Insurance, San Diego, California, February 28. "'Failure of Pathology to Explain Low Back Pain"; "Conservative Management of Low Back Pain."

The Puzzling Relationship of Vertigo and Cervical Spine, sponsored by the European Chiropractors' Union, Geneva, Switzerland, May 16 - 18. "Incidence, Risk Factors, and Mechanisms of Vertebral Basilar Artery Ischemia Following Cervical Manipulation"; "A Critical Analysis of Vertiginous Symptoms in the Prance of Chiropractic."

Palmer College of Chiropractic West, graduation ceremony, Santa Clara, California, June 14. Commencement Address: "Chiropractic is an Accepted Profession: What Do I Do Now?"

Recent Advances in the Treatment of Low Back Pain, 11th ISSLS Instructional Course sponsored by Hospital for Joint Diseases, New York City, June 22. "Indications for Clinical Neurophysiological Testing"; "Spinal Manipulation: When? How? Who?"

SPINE Combined Grand Rounds, sponsored by the University of New York, Syracuse, Department of Physical Medicine and Research, June 24. "The Failure of Pathological Model to Explain Back Pain and its Consequence in Guideline Development."

Chiropractic Managed Care: Developing Successful Integration Strategies, sponsored by the National Managed Health Care Congress, Coronado, California, July 23, "A New Proposal for Standardizing Health Care Providers"

17th Annual Occupational Spinal Disorders Conference: Return to Work with Pain; Crossing the Barrier, sponsored by Canadian Back Institute, Calgary, Alberta, Canada, September 15 - 16. "'Chiropractic: The second 100 years"; Session: The Barrier of Research. Topic: "why should we look?"

Diagnosis & Treatment of' Back Pain - The Next Level, sponsored by American Back Society and Saint Mary's Spine Center, San Francisco, California, December 12 - 14. "Credentialing of health care providers to qualify for managed care referral panels - including compliance with minimum standards and specific treatment protocols"; "Legitimization of manipulation - for who and how will you provide this treatment."

1997

Clinical Neurology in Chiropractic Practice, in Patients' Interest ~ sponsored by the international College of Australia Ltd. and Chiropractors Association of Australia, Sydney and Brisbane, Australia, February 15 - 16. Course lecturer on the clinical aspects of neurophysiology

1997 World Chiropractic Congress, sponsored by World Federation of Chiropractic, The Chiropractic Council of Japan The World Heath Organization Tokyo, Course chairman. "Cerebrovascular complications of manipulation - Our current level of understanding"; "The future of research into the role of manipulation in the treatment of the cervical spine.

American Academy of Pain Management 8th Annual Clinical Meeting, Las Vegas, Nevada, September 18. Workshop topic: "Lower back pain: Finding common ground - Chiropractic Perspective."

American Association of Electrodianostic Medicine 44th Annual Scientific Meetin, 20th Annual Courses and Workshops, San Diego, California, September 18. Special Interst Group Session topic: "Electrophysiologic studies in bowel and bladder problems and sexual dysfunction."

NCMIC 1997 Defense Counsel Seminar, presented by National Chiropractic Mutual Insurance Company, Chicago, Illinois, October 3 - 4. Lecture topic: "A new look at stroke: The facts of an exhaustive study."

Alternatives in Patient Care, conference sponsored by the College of Physicians of Columbia University and Oxford Health Plans, New York City, October 22. Presentation: "Chiropractic: Clinical Effectiveness and Contraindications."

The Diagnosis and Treatment of Neck and Back Pain - The integrative Approach, sponsored by American Back Society and Stanford University, San Francisco, California, December 10 -13. "Evidence that muscles play a role in back pain."

1998

Occupational Ergonomics: Work Evaluation and Prevention of Upper Limb and Back Disorders, sponsored by University of Michigan, American Industrial Hygiene Association (San Diego Local Section), and State Compensation Insurance Fund, San Diego, California, February 4. Presentations: "Failure of Pathology to Explain Low Back Pain", "Conservative Management of Low Back Pain."

Seventh Annual Workers' Compensation and Occupational Medicine Seminar, sponsored by SEAK, Inc., and The American College of Occupational and Environmental Medicine, San Francisco, California, March 11. Presentations: "Spinal Manipulation: Scientific Update," "Low Back Pain Risk Factors

Hospital for Joint Diseases Spine Center symposium: Management of Recalcitrant Back Disorders, sponsored by New York Chiropractic College, New York, New York, April 4. Presentations: "History and Physical: Red Hags," "International advances in chiropractic."

1998 California Chiropractic Association Convention, Clinical Concepts Workshops and Tug-of-War II, The Great Debate. San Diego, California, June 27.

North American Spine Society 13th Annual Meeting. Presentation: "Sixty-four cases of CVAs following cervical spine manipulative therapy." Symposium: "'Non-surgical Back Pain Management." San Francisco, California, October 30.

Canadian Heritage Conference, 1st Scientific Chiropractic Symposium, sponsored by the University of Calgary. Lecture: "The Evolution of Chiropractic Research: A Personal Perspective." Calgary, Alberta, November 15.

Palmer College of Chiropractic West, commencement speech at the graduation ceremony. "'The Search for a Post-Graduate Mentor." San Jose, California, December 11.

1999

Alternative Medicine: Implications for Clinical Practice and State-of-the-Science Symposia, sponsored by Harvard Medical School, Department of Continuing Education. Lecture: "Chiropractic." Boston, Massachusetts, February 28 - March 2.

Occupational Ergonomics: Work Evaluation and Prevention of Upper Limb and Back Disorders, sponsored by University of Michigan Center for Occupational Health and Safety Engineering and by American College of Occupational and Environmental Medicine. Lectures: "Failure of Pathology to Explain Low Back Pain, Conservative Management of Low Back Pain." San Diego, California, March I7.

World Federation of Chiropractic 5th WFC Congress and Conference. Lecture: "The Neurological Effects of the Adjustment." Auckland, New Zealand, May 20 - 22.

Advanced Diagnosis and Treatment of Neck and Back Pain: The Integrated Approach. Sponsored by American Back Society and St. Mary's Regional Medical Center. Lecture; "A Century of Progress in Spinal Care." Las Vegas, Nevada, December 9.

2000

Occupational Ergonomics: Work Evaluation and Prevention of Upper Limb and Back Disorders. Sponsored by University of' Michigan. Lecture: "Failure of Pathology to Explain Low Back Pain" and "Conservative Management of Low Back Pain." Los Angeles, California, March 1.

Complementary and Alternative Medicine symposia. Sponsored by Harvard Medical School, Department of Continuing Education. Lecture: "Chiropractic." Boston, Massachusetts, March 12.

Anglo-European College of Chiropractic/British Chiropractic Association Joint Conference. Lecture: "What is the relationship between spinal pain, disability, and pathology?" "Cervicogenic headaches - what is our current level of understanding?" "Research and interprofessional cooperation as the basis for future understanding of neck pain." Bournemouth, England, March

Canadian Memorial Chiropractic College, 55th Convocation Speech: "The importance of a mentor in maximizing the opportunities of a graduating chiropractor." Toronto, Canada, May 5.

Osteopathic Physicians and Surgeons of California 8th Annual Seminar. Guest speaker. Dana Point, California, June 2.

Michigan State University, College of Osteopathic Medicine. Patenge Distinguished Lecturer. "Evolution of manipulation research." Lansing, Michigan, July 20.

International Conference on Spinal Manipulation sponsored by Foundation for Chiropractic Education and Research, Minnesota Chiropractic Association, and Northwestern College of Chiropractic. Keynote presentation: "Strengths and weaknesses of current chiropractic neurological theories." Bloomington, Michigan, September 23.

Defense Counsel Seminar, presented by NCMIC Insurance Company. Presentation: "CVA: A clinical analysis." San Antonio, Texas, October 6.

Advanced Diagnosis and Treatment for Neck and Back Pain 2000, sponsored by American Back Society and Allegheny General Hospital. Lecture: "Differential diagnosis of back pain - has it changed?" Vancouver, B.C., December 7.

2001

Chiropractic Neurology Seminar', sponsored by the Israel Chiropractic Association. Topics of discussion: Current status of neurologic theories of chiropractic; Differential diagnosis of patients with spinal pain; Modern models to explain spinal pain~ Cervicogenic headaches; Grand rounds/presentation of cases. Lecture: "'Chiropractic and Spinal Manipulation. Integration into Modern Health Care." Workshop: "The neurological examination in the chiropractic office." Aviv, Israel, January I7 and 19.

Harvard Complimentary and Integrative Medicine Symposium, Harvard Medical School Department of Continuing Education. Lecture: "Chiropractic. Clinical Practice and State of the Science." Boston Massachusetts, February 11.

American Academy of Orthopedic Surgeons 68th Annual Meeting Scientific Program. Symposium: "Complementary and Alternative Medicine (CAM) and the Orthopedic Surgeon." San Francisco, California, February 28.

Occupational Ergonomics: Work Evaluation and Prevention of Upper Limb and Back Disorders. Sponsored by University of Michigan. Lecture: "Failure of pathology to explain low back pain." "Conservative management of low back pain." Los Angeles, California, Matte 12.

World Federation of Chiropractic 6th Biennial Congress. Lecture: "The role of" chiropractic in the management of neck pain back pain, and headaches." Workshop: "The basic neurological examination" Paris, France, May 25.

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Scott Haldeman, M.D.

THESES AND BOOKS

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3. Haldeman S (editor): Modern Developments in the Principles and Practice of Chiropractic Appleton-Century Crofts, New York 1980.

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2. Haldeman, S: "Observations Made Under Test Conditions with the Synchro-Therme." J. Can. Chiropr. Assn. 14 (3): 9-12, 1970.

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4. Haldeman S, Drum, D: "The Compression Subluxation." J. Clin. Chiropr. Arch. I: 10-21, 1971.

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14. Haldeman, S: "Histamine: The Ultimate Stimulator of Gastric Acid Secretion?." J Can. Chiropr Assn. 16 3: 25-29, 1972.

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U.S. Supreme Court

COPPERWELD CORP. v. INDEPENDENCE TUBE CORP., 467 U.S. 752 (1984)

467 U.S. 752

COPPERWELD CORP. ET AL. v. INDEPENDENCE TUBE CORP.
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

No. 82-1260.

Argued December 5, 1983
Decided June 19, 1984

Petitioner Copperweld Corp. purchased petitioner Regal Tube Co., a manufacturer of steel tubing, from Lear Siegler, Inc., which had operated Regal as an unincorporated division, and which under the sale agreement was bound not to complete with Regal for five years. Copperweld then transferred Regal's assets to a newly formed, wholly owned subsidiary. Shortly before Copperweld acquired Regal, David Grohne, who previously had been an officer of Regal, became an officer of Lear Siegler, and, while continuing to work for Lear Siegler, formed respondent corporation to compete with Regal. Respondent then gave Yoder Co. a purchase order for a tubing mill, but Yoder voided the order when it received a letter from Copperweld warning that Copperweld would be greatly concerned if Grohne contemplated competing with Regal and promising to take the necessary steps to protect Copperweld's rights under the noncompetition agreement with Lear Siegler. Respondent then arranged to have a mill supplied by another company. Thereafter respondent filed an action in Federal District Court against petitioners and Yoder. The jury found, inter alia, that petitioners had

conspired to violate 1 of the Sherman Act but that Yoder was not part of the conspiracy, and awarded treble damages against petitioners. The Court of Appeals affirmed. Noting that the exoneration of Yoder from antitrust liability left a parent corporation and its wholly owned subsidiary as the only parties to the 1 conspiracy, the court questioned the wisdom of subjecting an "intra-enterprise" conspiracy to antitrust liability, but held that such liability was appropriate "when there is enough separation between the two entities to make treating them as two independent actors sensible," and that there was sufficient evidence for the jury to conclude that Regal was more like a separate corporate entity than a mere service arm of the parent.

Held: Petitioner Copperweld and its wholly owned subsidiary, petitioner Regal, are incapable of conspiring with each other for purposes of 1 of the Sherman Act. Pp. 759-777.

(a) While this Court has previously seemed to acquiesce in the "intra-enterprise conspiracy" doctrine, which provides that 1 liability is not [467 U.S. 752, 753] foreclosed merely because a parent and its subsidiary are subject to common ownership, the Court has never explored or analyzed in detail the justifications for such a rule. Pp. 759-766.

(b) Section 1 of the Sherman Act, in contrast to 2, reaches unreasonable restraints of trade effected by a "contract, combination . . . or conspiracy" between separate entities, and does not reach conduct that is "wholly unilateral." Pp. 767-769.

(c) The coordinated activity of a parent and its wholly owned subsidiary must be viewed as that of a single enterprise for purposes of 1 of the Sherman Act. A parent and its wholly owned subsidiary have

a complete unity of interest. Their objectives are common, not disparate, and their general corporate objectives are guided or determined not by two separate corporate consciousnesses, but one. With or without a formal "agreement," the subsidiary acts for the parent's benefit. If the parent and subsidiary "agree" to a course of action, there is no sudden joining of economic resources that had previously served different interests, and there is no justification for 1 scrutiny. In reality, the parent and subsidiary always have a "unity of purpose or a common design." The "intra-enterprise conspiracy" doctrine relies on artificial distinctions, looking to the form of an enterprise's structure and ignoring the reality. Antitrust liability should not depend on whether a corporate subunit is organized as an unincorporated division or a wholly owned subsidiary. Here, nothing in the record indicates any meaningful difference between Regal's operations as an unincorporated division of Lear Siegler and its later operations as a wholly owned subsidiary of Copperweld. Pp. 771-774.

(d) The appropriate inquiry in this case is not whether the coordinated conduct of a parent and its wholly owned subsidiary may ever have anticompetitive effects or whether the term "conspiracy" will bear a literal construction that includes a parent and its subsidiaries, but rather whether the logic underlying Congress' decision to exempt unilateral conduct from scrutiny under 1 of the Sherman Act similarly excludes the conduct of a parent and subsidiary. It can only be concluded that the coordinated behavior of a parent and subsidiary falls outside the reach of 1. Any anticompetitive activities of corporations and their wholly owned subsidiaries meriting antitrust remedies may be

policed adequately without resort to an "intra-enterprise conspiracy" doctrine. A corporation's initial acquisition of control is always subject to scrutiny under 1 of the Sherman Act and 7 of the Clayton Act, and thereafter the enterprise is subject to 2 of the Sherman Act and 5 of the Federal Trade Commission Act. Pp. 774-777.

691 F.2d 310, reversed. [467 U.S. 752, 754]

BURGER, C. J., delivered the opinion of the Court, in which BLACKMUN, POWELL, REHNQUIST, and O'CONNOR, JJ., joined. STEVENS, J., filed a dissenting opinion, in which BRENNAN and MARSHALL, JJ., joined, post, p. 778. WHITE, J., took no part in the consideration or decision of the case.

Erwin N. Griswold argued the cause for petitioners. With him on the briefs were William R. Jentes, Sidney N. Herman, Robert E. Shapiro, and Donald I. Baker.

Deputy Solicitor General Wallace argued the cause for the United States as amicus curiae urging reversal. With him on the brief were Solicitor General Lee, Assistant Attorney General Baxter, Deputy Assistant Attorney General Collins, Carolyn F. Corwin, Barry Grossman, and Nancy C. Garrison.

Victor E. Grimm argued the cause for respondent. With him on the brief were John R. Myers and Scott M. Mendel.

J. Randolf Wilson, Russel H. Carpenter, Jr., Stephen A. Bokat, Cynthia Wicker, William E. Blasier, and Quentin Riegel filed a brief for the Chamber of Commerce of the United States et al. as amici curiae urging reversal.

A brief of amici curiae urging affirmance was filed for the State of Alabama et al. by Robert K. Corbin, Attorney General of Arizona, and Richard A. Alcorn and Charles L. Eger, Assistant Attorneys General; Charles A. Graddick, Attorney General of Alabama, and Richard Owen, Assistant Attorney General; John Steven Clark, Attorney General of Arkansas, and Jeffrey A. Bell, Assistant Attorney General; Duane Woodard, Attorney General of Colorado, and Thomas P. McMahon, Assistant Attorney General; Neil F. Hartigan, Attorney General of Illinois, and Robert E. Davy, Assistant Attorney General; Thomas J. Miller, Attorney General of Iowa, and John R. Perkins, Assistant Attorney General; Robert T. Stephan, Attorney General of Kansas, and Wayne E. Hundley, Deputy Attorney General; Steven L. Beshear, Attorney General of Kentucky, and James M. Ringo, Assistant Attorney General; Hubert H. Humphrey III, Attorney General of Minnesota, and Stephen P. Kilgriff, Assistant Attorney General; Bill Allain, Attorney General of Mississippi, and Robert Sanders, Special Assistant Attorney General; Mike Greely, Attorney General of Montana, and Joe R. Roberts, Assistant Attorney General; Paul L. Douglas, Attorney General of Nebraska, and Dale A. Comer, Assistant Attorney General; Robert O. Wefald, Attorney General of North Dakota, and Alan C. Hoberg, Assistant Attorney General; Michael C. Turpen, Attorney [467 U.S. 752, 755] General of Oklahoma, and James B. Franks, Assistant Attorney General; Dave Frohnmayer, Attorney General of Oregon; John J. Easton, Jr., Attorney General of Vermont, and Glenn R. Jarrett, Assistant Attorney General; Ken Eikenberry, Attorney General of Washington, John R. Ellis, Deputy Attorney General, and Jon P. Ferguson, Assistant Attorney General; Bronson C. La Follette, Attorney General of Wisconsin, and Michael L. Zaleski, Assistant Attorney General; Joseph I. Lieberman, Attorney General of Connecticut, and Robert M. Langer, Assistant Attorney General; Charles M. Oberly, Attorney General of Delaware, and Vincent M. Amberly, Deputy Attorney

General; James E. Tierney, Attorney General of Maine, and Stephen L. Wessler, Senior Assistant Attorney General; Stephen H. Sachs, Attorney General of Maryland, and Charles O. Monk II, Assistant Attorney General; Frank J. Kelley, Attorney General of Michigan, and Edwin M. Bladen, Assistant Attorney General; Paul Bardacke, Attorney General of New Mexico; Rufus L. Edmisten, Attorney General of North Carolina, and H. A. Cole, Jr., Special Deputy Attorney General; Dennis J. Roberts II, Attorney General of Rhode Island, and Faith A. LaSalle, Special Assistant Attorney General; Mark V. Meierhenry, Attorney General of South Dakota, and Dennis R. Holmes, Deputy Attorney General; William M. Leech, Jr., Attorney General of Tennessee, and William J. Haynes, Jr., Deputy Attorney General; David L. Wilkinson, Attorney General of Utah, Stephen G. Schwendiman, Chief, Assistant Attorney General, and Suzanne M. Dallimore, Assistant Attorney General; A. G. McClintock, Attorney General of Wyoming, and Gay Vanderpoel, Senior Assistant Attorney General; Inez Smith Reid, Acting Corporation Council for the District of Columbia, and Francis S. Smith, Assistant Corporation Council.

Briefs of amici curiae were filed for the Canadian Manufacturers Association et al. by John DeQ. Briggs III, Scott E. Flick, and Jan Schneider; and for Kaiser Aluminum & Chemical Corporation by Milton Handler and John A. Moore. [467 U.S. 752, 755]

CHIEF JUSTICE BURGER delivered the opinion of the Court.

We granted certiorari to determine whether a parent corporation and its wholly owned subsidiary are legally capable of conspiring with each other under 1 of the Sherman Act.

I

A

The predecessor to petitioner Regal Tube Co. was established in Chicago in 1955 to manufacture structural steel [467 U.S. 752, 756] tubing used in heavy equipment, cargo vehicles, and construction. From 1955 to 1968 it remained a wholly owned subsidiary of C. E. Robinson Co. In 1968 Lear Siegler, Inc., purchased Regal Tube Co. and operated it as an unincorporated division. David Grohne, who had previously served as vice president and general manager of Regal, became president of the division after the acquisition.

In 1972 petitioner Copperweld Corp. purchased the Regal division from Lear Siegler; the sale agreement bound Lear Siegler and its subsidiaries not to compete with Regal in the United States for five years. Copperweld then transferred Regal's assets to a newly formed, wholly owned Pennsylvania corporation, petitioner Regal Tube Co. The new subsidiary continued to conduct its manufacturing operations in Chicago but shared Copperweld's corporate headquarters in Pittsburgh.

Shortly before Copperweld acquired Regal, David Grohne accepted a job as a corporate officer of Lear Siegler. After the acquisition, while continuing to work for Lear Siegler, Grohne set out to establish his own steel tubing business to compete in the same market as Regal. In May 1972 he formed respondent Independence Tube Corp., which soon secured an offer from the Yoder Co. to supply a tubing mill. In December 1972 respondent gave Yoder a purchase order to have a mill ready by the end of December 1973.

When executives at Regal and Copperweld learned of Grohne's plans, they initially hoped that Lear Siegler's noncompetition agreement would thwart the new competitor. Although their lawyer advised them that Grohne was not bound by the agreement, he did suggest that petitioners might obtain an injunction against Grohne's activities if he made use of any technical information or trade secrets belonging to Regal. The legal opinion was given to Regal and Copperweld along with a letter to be sent to anyone with whom Grohne attempted to deal. The letter warned that Copperweld would be "greatly concerned if [Grohne] contemplates [467 U.S. 752, 757] entering the structural tube market . . . in competition with Regal Tube" and promised to take "any and all steps which are necessary to protect our rights under the terms of our purchase agreement and to protect the know-how, trade secrets, etc., which we purchased from Lear Siegler." Petitioners later asserted that the letter was intended only to prevent third parties from developing reliance interests that might later make a court reluctant to enjoin Grohne's operations.

When Yoder accepted respondent's order for a tubing mill on February 19, 1973, Copperweld sent Yoder one of these letters; two days later Yoder voided its acceptance. After respondent's efforts to resurrect the deal failed, respondent arranged to have a mill supplied by another company, which performed its agreement even though it too received a warning letter from Copperweld. Respondent began operations on September 13, 1974, nine months later than it could have if Yoder had supplied the mill when originally agreed.

Although the letter to Yoder was petitioners' most successful effort to discourage those contemplating doing business with respondent, it was not their only one. Copperweld repeatedly contacted banks that were considering financing respondent's operations. One or both

petitioners also approached real estate firms that were considering providing plant space to respondent and contacted prospective suppliers and customers of the new company.

B

In 1976 respondent filed this action in the District Court against petitioners and Yoder.[1] The jury found that [467 U.S. 752, 758] Copperweld and Regal had conspired to violate 1 of the Sherman Act, 26 Stat. 209, as amended, 15 U.S.C. 1, but that Yoder was not part of the conspiracy. It also found that Copperweld, but not Regal, had interfered with respondent's contractual relationship with Yoder; that Regal, but not Copperweld, had interfered with respondent's contractual relationship with a potential customer of respondent, Deere Plow & Planter Works, and had slandered respondent to Deere; and that Yoder had breached its contract to supply a tubing mill.

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[1] The chairman of the board and chief executive officer of both Copperweld and Regal, Phillip H. Smith, was also named as a defendant. In addition, respondents originally charged petitioners and Smith with an attempt to monopolize the market for structural steel tubing in violation of 2 of the Sherman Act, 26 Stat. 209, as amended, 15 U.S.C. 2. Before [467 U.S. 752, 758] trial respondent dismissed Smith as a defendant and dismissed its 2 monopolization count.

Petitioners counterclaimed on the ground that respondent and Grohne had used proprietary information belonging to Regal, had competed unfairly by hiring away key Regal personnel, and had interfered with prospective business relationships by filing the lawsuit on the eve of a large Copperweld debenture offering. At the close of the evidence, the court directed a verdict against petitioners on their counterclaims. The disposition of these claims is not at issue before this Court.

At a separate damages phase, the judge instructed the jury that the damages for the antitrust violation and for the inducement of the Yoder contract breach should be identical and not double counted. The jury then awarded $2,499,009 against petitioners on the antitrust claim, which was trebled to $7,497,027. It awarded $15,000 against Regal alone on the contractual interference and slander counts pertaining to Deere. The court also awarded attorney's fees and costs after denying petitioners' motions for judgment n.o.v. and for a new trial.

C

The United States Court of Appeals for the Seventh Circuit affirmed. 691 F.2d 310 (1982). It noted that the exoneration of Yoder from antitrust liability left a parent corporation and its wholly owned subsidiary as the only parties to the § 1 conspiracy. The court questioned the wisdom of subjecting an "intra-enterprise" conspiracy to antitrust liability, when the same conduct by a corporation and an unincorporated [467 U.S. 752, 759] division would escape liability for lack of the requisite two legal persons. However, relying on its decision in Photovest Corp. v. Fotomat Corp., 606 F.2d 704 (1979), cert. denied, 445 U.S. 917 (1980), the Court of Appeals held that liability was appropriate "when there is enough separation between the two entities to make treating them as two independent actors sensible." 691 F.2d, at 318. It held that the jury instructions took account of the proper factors for determining how much separation Copperweld and Regal

in fact maintained in the conduct of their businesses.[2] It also held that there was sufficient evidence for the jury to conclude that Regal was more like a separate corporate entity than a mere service arm of the parent.

We granted certiorari to reexamine the intra-enterprise conspiracy doctrine, 462 U.S. 1131 (1983), and we reverse.

II

Review of this case calls directly into question whether the coordinated acts of a parent and its wholly owned subsidiary can, in the legal sense contemplated by 1 of the Sherman Act, constitute a combination or conspiracy.[3] The so-called "intra-enterprise conspiracy" doctrine provides that 1 liability is not foreclosed merely because a parent and its subsidiary are subject to common ownership. The

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[2] The jury was instructed to consider many different factors: for instance, whether Copperweld and Regal had separate management staffs, separate corporate officers, separate clients, separate records and bank accounts, separate corporate offices, autonomy in setting policy, and so on. The jury also was instructed to consider "any other facts that you find are relevant to a determination of whether or not Copperweld and Regal are separate and distinct companies." App. to Pet. for Cert. B-9.

[3] Section 1 of the Sherman Act provides in pertinent part:

> "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony." 26 Stat. 209, as amended, 15 U.S.C. 1.

doctrine derives from declarations in several of this Court's opinions. [467 U.S. 752, 760]

In no case has the Court considered the merits of the intra-enterprise conspiracy doctrine in depth. Indeed, the concept arose from a far narrower rule. Although the Court has expressed approval of the doctrine on a number of occasions, a finding of intra-enterprise conspiracy was in all but perhaps one instance unnecessary to the result.

The problem began with United States v. Yellow Cab Co., 332 U.S. 218 (1947). The controlling shareholder of the Checker Cab Manufacturing Corp., Morris Markin, also controlled numerous companies operating taxicabs in four cities. With few exceptions, the operating companies had once been independent and had come under Markin's control by acquisition or merger. The complaint alleged conspiracies under 1 and 2 of the Sherman Act among Markin, Checker, and five corporations in the operating system. The Court stated that even restraints in a vertically integrated enterprise were not "necessarily" outside of the Sherman Act, observing that an unreasonable restraint

> "may result as readily from a conspiracy among those who are affiliated or integrated under common ownership as from a conspiracy among those who are otherwise independent. Similarly, any affiliation or integration flowing from an illegal conspiracy cannot insulate the conspirators from the sanctions which Congress has imposed. The corporate interrelationships of the conspirators, in other words, are not determinative of the applicability of the Sherman Act. That statute is aimed at substance rather than form. See Appalachian

Coals, Inc. v. United States, 288 U.S. 344, 360 - 361, 376-377.

"And so in this case, the common ownership and control of the various corporate appellees are impotent to liberate the alleged combination and conspiracy from the impact of the Act. The complaint charges that the restraint of interstate trade was not only effected by the combination of the appellees but was the primary object [467 U.S. 752, 761] of the combination. The theory of the complaint . . . is that `dominating power' over the cab operating companies `was not obtained by normal expansion . . . but by deliberate, calculated purchase for control.'" Id., at 227-228 (emphasis added) (quoting United States v. Reading Co., 253 U.S. 26, 57 (1920)).

It is the underscored language that later breathed life into the intra-enterprise conspiracy doctrine. The passage as a whole, however, more accurately stands for a quite different proposition. It has long been clear that a pattern of acquisitions may itself create a combination illegal under 1, especially when an original anticompetitive purpose is evident from the affiliated corporations' subsequent

conduct.[4] The Yellow Cab passage is most fairly read in light of this settled rule. In Yellow Cab, the affiliation of the defendants was irrelevant because the original acquisitions were themselves illegal.[5] An affiliation "flowing from an illegal conspiracy" would not avert sanctions. Common ownership and control were irrelevant because restraint of trade was "the primary object of the combination," which was created in a "`deliberate, [467 U.S. 752, 762] calculated'" manner. Other language in the opinion is to the same effect.[6]

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[4] Under the arrangements condemned in Northern Securities Co. v. United States, 193 U.S. 197, 354 (1904) (plurality opinion), "all the stock [a railroad holding company] held or acquired in the constituent companies was acquired and held to be used in suppressing competition between those companies. It came into existence only for that purpose." In Standard Oil Co. v. United States, 221 U.S. 1 (1911), and United States v. American Tobacco Co., 221 U.S. 106 (1911), the trust or holding company device brought together previously independent firms to lessen competition and achieve monopoly power. Although the Court in the latter case suggested that the contracts between affiliated companies, and not merely the original combination, could be viewed as the conspiracy, id., at 184, the Court left no doubt that "the combination in and of itself" was a restraint of trade and a monopolization, id., at 187.

[5] Contrary to the dissent's suggestion, post, at 779, 788, n. 18, our point is not that Yellow Cab found only the initial acquisition illegal; our point is that the illegality of the initial acquisition was a predicate for its holding that any postacquisition conduct violated the Act.

[6] When discussing the fact that some of the affiliated Chicago operating companies did not compete to obtain exclusive transportation contracts held by another of the affiliated companies, the Court stated:

> "[T]he fact that the competition restrained is that between affiliated corporations cannot serve to

The Court's opinion relies on Appalachian Coals, Inc. v. United States, 288 U.S. 344 (1933); however, examination of that case reveals that it gives very little support for the broad doctrine Yellow Cab has been thought to announce. On the contrary, the language of Chief Justice Hughes speaking for the Court in Appalachian Coals supports a contrary conclusion. After observing that "[t]he restrictions

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> negative the statutory violation where, as here, the affiliation is assertedly one of the means of effectuating the illegal conspiracy not to compete." 332 U.S., at 229 (emphasis added).

The passage quoted in text is soon followed by a cite to United States v. Crescent Amusement Co., 323 U.S. 173, 189 (1944). Crescent Amusement found violations of 1 and 2 by film exhibitors affiliated (in most cases) by 50 percent ownership. The exhibitors used the monopoly power they possessed in certain towns to force film distributors to give them favorable terms in other towns. The Court found it unnecessary to view the distributors as part of the conspiracy, id., at 183, so the Court plainly viewed the affiliated entities themselves as the conspirators. The Crescent Amusement Court, however, in affirming an order of divestiture, noted that such a remedy was appropriate when "creation of the combination is itself the violation." Id., at 189. This suggests that both Crescent Amusement and Yellow Cab, which cited the very page on which this passage appears, stand for a narrow rule based on the original illegality of the affiliation.

The dissent misconstrues a later passage in Crescent Amusement stating that divestiture need not be limited to those affiliates whose "acquisition was part of the fruits of the conspiracy," 323 U.S., at 189 . See post, at 780-781. This meant only that divestiture could apply to affiliates other than those who were driven out of business by the practices of the original conspirators and who were then acquired illegally to increase the combination's monopoly power. See 323 U.S., at 181 . It did not mean that affiliates acquired for lawful purposes were subject to divestiture.

the Act imposes are not mechanical or artificial," 288 U.S., at 360, he went on to state: [467 U.S. 752, 763]

> "The argument that integration may be considered a normal expansion of business, while a combination of independent producers in a common selling agency should be treated as abnormal - that one is a legitimate enterprise and the other is not - makes but an artificial distinction. The Anti-Trust Act aims at substance." Id., at 377. [7]

As we shall see, infra, at 771-774, it is the intra-enterprise conspiracy doctrine itself that "makes but an artificial distinction" at the expense of substance.

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[7] Appalachian Coals does state that the key question is whether there is an unreasonable restraint of trade or an attempt to monopolize. "If there is, the combination cannot escape because it has chosen corporate form; and, if there is not, it is not to be condemned because of the absence of corporate integration." 288 U.S., at 377. Appalachian Coals, however, validated a cooperative selling arrangement among independent entities. The statement that intracorporate relationships would be subject to liability under 1 is thus dictum. The statement may also envision merely the limited rule in Yellow Cab pertaining to acquisitions that are themselves anticompetitive.

The ambiguity of the Yellow Cab holding yielded the one case giving support to the intra-enterprise conspiracy doctrine.[8] In Kiefer-Stewart Co. v. Joseph E. Seagram & Sons, Inc., 340 U.S. 211 (1951), the Court held that two wholly owned subsidiaries of a liquor distiller were guilty under 1 of the Sherman Act for jointly refusing to supply a wholesaler who declined to abide by a maximum resale pricing scheme. The Court offhandedly dismissed the defendant's argument [467 U.S. 752, 764] that "their status as `mere instrumentalities of a single manufacturing-merchandizing unit' makes it impossible for them to have conspired in a manner forbidden by the Sherman Act." Id., at 215. With only a citation to Yellow Cab and no further analysis, the Court stated that the

> "suggestion runs counter to our past decisions that common ownership and control does not liberate corporations from the impact of the antitrust laws"

and stated that this rule was "especially applicable" when defendants "hold themselves out as competitors." 340 U.S., at 215.

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[8] In two cases decided soon after Yellow Cab on facts similar to Crescent Amusement, see n. 6, supra, affiliated film exhibitors were found to have conspired in violation of 1. Schine Chain Theatres, Inc. v. United States, 334 U.S. 110 (1948); United States v. Griffith, 334 U.S. 100 (1948). Griffith simply assumed that the companies were capable of conspiring with each other; Schine cited Yellow Cab and Crescent Amusement for the proposition, 334 U.S., at 116. In both cases, however, an intra-enterprise conspiracy holding was unnecessary not only because the Court found a 2 violation, but also because the affiliated exhibitors had conspired with independent film distributors. See ibid.; Griffith, supra, at 103, n. 6, 109.

Unlike the Yellow Cab passage, this language does not pertain to corporations whose initial affiliation was itself unlawful. In straying beyond Yellow Cab, the Kiefer-Stewart Court failed to confront the anomalies an intra-enterprise doctrine entails. It is relevant nonetheless that, were the case decided today, the same result probably could be justified on the ground that the subsidiaries conspired with wholesalers other than the plaintiff.[9] An intra-enterprise conspiracy doctrine thus would no longer be necessary to a finding of liability on the facts of Kiefer-Stewart.

Later cases invoking the intra-enterprise conspiracy doctrine do little more than cite Yellow Cab or Kiefer-Stewart, and in none of the cases was the doctrine necessary to the result reached. Timken Roller Bearing Co. v. United States, 341 U.S. 593 (1951), involved restrictive horizontal agreements [467 U.S. 752, 765] between an American corporation and two foreign corporations in which it owned 30 and 50 percent interests respectively. The Timken Court cited Kiefer-Stewart to show that "[t]he fact that there is common ownership or control of the contracting corporations does not liberate them from the impact of the antitrust laws." 341 U.S., at 598 . But the relevance of this statement is unclear. The American defendant in Timken did not own a majority interest in either of the foreign

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[9] Although the plaintiff apparently never acquiesced in the resale price maintenance scheme, Kiefer-Stewart Co. v. Joseph E. Seagram & Sons, Inc., 182 F.2d 228, 231 (CA7 1950), rev'd, 340 U.S. 211 (1951), one of the subsidiaries did gain the compliance of other wholesalers after once terminating them for refusing to abide by the pricing scheme. See 182 F.2d, at 231; 340 U.S., at 213 . A theory of combination between the subsidiaries and the wholesalers could now support 1 relief, whether or not it could have when Kiefer-Stewart was decided. See Albrecht v. Herald Co., 390 U.S. 145, 149 -150, and n. 6 (1968); United States v. Parke, Davis & Co., 362 U.S. 29 (1960).

corporate conspirators and, as the District Court found, it did not control them.[10] Moreover, as in Yellow Cab, there was evidence that the stock acquisitions were themselves designed to effectuate restrictive practices.[11] The Court's reliance on the intra-enterprise conspiracy doctrine was in no way necessary to the result.

The same is true of Perma Life Mufflers, Inc. v. International Parts Corp., 392 U.S. 134 (1968), which involved a conspiracy among a parent corporation and three subsidiaries to impose various illegal restrictions on plaintiff franchisees. The Court did suggest that, because the defendants

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[10] See United States v. Timken Roller Bearing Co., 83 F. Supp. 284, 311-312 (ND Ohio 1949), aff'd as modified, 341 U.S. 593 (1951). The agreement of an individual named Dewar, who owned 24 and 50 percent of the foreign corporations respectively, was apparently required for the American defendant to have its way.

[11] For almost 20 years before they became affiliated by stock ownership, two of the corporations had been party to the sort of restrictive agreements the Timken Court condemned. Three Justices upholding antitrust liability were of the view that Timken's "interests in the [foreign] companies were obtained as part of a plan to promote the illegal trade restraints" and that the "intercorporate relationship" was "the core of the conspiracy." Id., at 600-601. Because two Justices found no antitrust violation at all, see id., at 605 (Frankfurter, J., dissenting); id., at 606 (Jackson, J., dissenting), and two Justices did not take part, apparently only Chief Justice Vinson and Justice Reed were prepared to hold that there was a violation even if the initial acquisition itself was not illegal. See id., at 601-602 (Reed, J., joined by Vinson, C. J., concurring).

> "availed themselves of the privilege of doing business through separate corporations, the fact of common ownership [467 U.S. 752, 766] could not save them from any of the obligations that the law imposes on separate entities [citing Yellow Cab and Timken]." Id., at 141-142.

But the Court noted immediately thereafter that "[i]n any event" each plaintiff could "clearly" charge a combination between itself and the defendants or between the defendants and other franchise dealers. Ibid. Thus, for the same reason that a finding of liability in Kiefer-Stewart could today be justified without reference to the intra-enterprise conspiracy doctrine, see n. 9, supra, the doctrine was at most only an alternative holding in Perma Life Mufflers.

In short, while this Court has previously seemed to acquiesce in the intra-enterprise conspiracy doctrine, it has never explored or analyzed in detail the justifications for such a rule; the doctrine has played only a relatively minor role in the Court's Sherman Act holdings.

III

Petitioners, joined by the United States as amicus curiae, urge us to repudiate the intra-enterprise conspiracy doctrine.[12] The central criticism is that the doctrine gives undue significance to the fact that a subsidiary is separately incorporated and thereby treats as the concerted activity of two [467 U.S. 752, 767] entities what is really unilateral behavior flowing from decisions of a single enterprise.

We limit our inquiry to the narrow issue squarely presented: whether a parent and its wholly owned subsidiary are capable of conspiring in violation of 1 of the Sherman Act. We do not consider under what circumstances, if any, a parent may be liable for conspiring with an affiliated corporation it does not completely own.

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[12] The doctrine has long been criticized. See, e. g., Areeda, Intra-enterprise Conspiracy in Decline, 97 Harv. L. Rev. 451 (1983); Handler & Smart, The Present Status of the Intracorporate Conspiracy Doctrine, 3 Cardozo L. Rev. 23 (1981); Kempf, Bathtub Conspiracies: Has Seagram Distilled a More Potent Brew?, 24 Bus. Law. 173 (1968); McQuade, Conspiracy, Multicorporate Enterprises, and Section 1 of the Sherman Act, 41 Va. L. Rev. 183 (1955); Rahl, Conspiracy and the Anti-Trust Laws, 44 Ill. L. Rev. 743 (1950); Sprunk, Intra-Enterprise Conspiracy, 9 ABA Antitrust Section Rep. 20 (1956); Stengel, Intra-Enterprise Conspiracy Under Section 1 of the Sherman Act, 35 Miss. L. J. 5 (1963); Willis & Pitofsky, Antitrust Consequences of Using Corporate Subsidiaries, 43 N. Y. U. L. Rev. 20 (1968); Note, "Conspiring Entities" Under Section 1 of the Sherman Act, 95 Harv. L. Rev. 661 (1982); Note, Intra-Enterprise Conspiracy Under Section 1 of the Sherman Act: A Suggested Standard, 75 Mich. L. Rev. 717 (1977).

A

The Sherman Act contains a "basic distinction between concerted and independent action." Monsanto Co. v. Spray-Rite Service Corp., 465 U.S. 752, 761 (1984). The conduct of a single firm is governed by 2 alone and is unlawful only when it threatens actual monopolization.[13] It is not enough that a single firm appears to "restrain trade" unreasonably, for even a vigorous competitor may leave that impression. For instance, an efficient firm may capture unsatisfied customers from an inefficient rival, whose own ability to compete may suffer as a result. This is the rule of the marketplace and is precisely the sort of competition that promotes the consumer interests that the Sherman Act aims

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13 Section 2 of the Sherman Act provides in pertinent part:

> "Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony." 26 Stat. 209, as amended, 15 U.S.C. 2. By making a conspiracy to monopolize unlawful, 2 does reach both concerted and unilateral behavior. The point remains, however, that purely unilateral conduct is illegal only under 2 and not under 1. Monopolization without conspiracy is unlawful under 2, but restraint of trade without a conspiracy or combination is not unlawful under 1.

to foster.[14] In part because it is sometimes difficult to [467 U.S. 752, 768] distinguish robust competition from conduct with long-run anticompetitive effects, Congress authorized Sherman Act scrutiny of single firms only when they pose a danger of monopolization. Judging unilateral conduct in this manner reduces the risk that the antitrust laws will dampen the competitive zeal of a single aggressive entrepreneur.

Section 1 of the Sherman Act, in contrast, reaches unreasonable restraints of trade effected by a "contract, combination . . . or conspiracy" between separate entities. It does not reach conduct that is "wholly unilateral." Albrecht v. Herald Co., 390 U.S. 145, 149 (1968); accord, Monsanto Co. v. Spray-Rite Corp., supra, at 761. Concerted activity subject to 1 is judged more sternly than unilateral activity under 2. Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal per se without inquiry into the harm it has actually caused. See generally Northern Pacific R. Co. v. United States, 356 U.S. 1, 5 (1958). Other combinations, such as mergers, joint ventures, and various vertical agreements, hold the promise of increasing a firm's efficiency and enabling it to compete more effectively. Accordingly, such combinations are judged under a rule of reason, an inquiry into market power and market structure designed to assess the combination's actual effect. See, e. g., Continental T. V., Inc. v. GTE Sylvania Inc., 433 U.S. 36 (1977); Chicago Board

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[14] For example, the Court has declared that 2 does not forbid market power to be acquired "as a consequence of a superior product, [or] business acumen." United States v. Grinnell Corp., 384 U.S. 563, 571 (1966). We have also made clear that the "antitrust laws . . . were enacted for `the protection of competition, not competitors.'" Brunswick Corp. v. Pueblo [467 U.S. 752, 768] Bowl-O-Mat, Inc., 429 U.S. 477, 488 (1977) (damages for violation of Clayton Act 7) (quoting Brown Shoe Co. v. United States, 370 U.S. 294, 320 (1962)).

of Trade v. United States, 246 U.S. 231 (1918). Whatever form the inquiry takes, however, it is not necessary to prove that concerted activity threatens monopolization.

The reason Congress treated concerted behavior more strictly than unilateral behavior is readily appreciated. Concerted activity inherently is fraught with anticompetitive [467 U.S. 752, 769] risk. It deprives the marketplace of the independent centers of decisionmaking that competition assumes and demands. In any conspiracy, two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit. This not only reduces the diverse directions in which economic power is aimed but suddenly increases the economic power moving in one particular direction. Of course, such mergings of resources may well lead to efficiencies that benefit consumers, but their anticompetitive potential is sufficient to warrant scrutiny even in the absence of incipient monopoly.

B

The distinction between unilateral and concerted conduct is necessary for a proper understanding of the terms "contract, combination . . . or conspiracy" in 1. Nothing in the literal meaning of those terms excludes coordinated conduct among officers or employees of the same company. But it is perfectly plain that an internal "agreement" to implement a single, unitary firm's policies does not raise the antitrust dangers that 1 was designed to police. The officers of a single firm are not separate economic actors pursuing separate economic interests, so agreements among them do not suddenly bring together economic power that was previously pursuing divergent goals. Coordination within a firm is as likely to result from an effort to compete as from an effort to stifle competition. In the marketplace, such coordination may be necessary if a

business enterprise is to compete effectively. For these reasons, officers or employees of the same firm do not provide the plurality of actors imperative for a 1 conspiracy.[15] [467 U.S. 752, 770]

There is also general agreement that 1 is not violated by the internally coordinated conduct of a corporation and

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[15] See, e. g., Schwimmer v. Sony Corp. of America, 677 F.2d 946, 953 (CA2), cert. denied, 459 U.S. 1007 (1982); Tose v. First Pennsylvania Bank, N. A., 648 F.2d 879, 893-894 (CA3), cert. denied, 454 U.S. 893 (1981); Morton Buildings of Nebraska, Inc. v. Morton Buildings, Inc., 531 F.2d 910, 916-917 (CA8 1976); Greenville Publishing Co. v. Daily Reflector, [467 U.S. 752, 770] Inc., 496 F.2d 391, 399 (CA4 1974) (dictum); Chapman v. Rudd Paint & Varnish Co., 409 F.2d 635, 643, n. 9 (CA9 1969); Poller v. Columbia Broadcasting System, Inc., 109 U.S. App. D.C. 170, 174, 284 F.2d 599, 603 (1960), rev'd on other grounds, 368 U.S. 464 (1962); Nelson Radio & Supply Co. v. Motorola, Inc., 200 F.2d 911, 914 (CA5 1952), cert. denied, 345 U.S. 925 (1953). Accord, Report of the Attorney General's National Committee to Study the Antitrust Laws 31 (1955). At the same time, many courts have created an exception for corporate officers acting on their own behalf. See, e. g., H & B Equipment Co. v. International Harvester Co., 577 F.2d 239, 244 (CA5 1978) (dictum); Greenville Publishing, supra; Johnston v. Baker, 445 F.2d 424, 427 (CA3 1971). Nothing in the language of the Sherman Act is inconsistent with the view that corporations cannot conspire with their own officers. It is true that a "person" under the Act includes both an individual and a corporation. 15 U.S.C. 7. But 1 does not declare every combination between two "persons" to be illegal. Instead it makes liable every "person" engaging in a combination or conspiracy "hereby declared to be illegal." As we note, the principles governing 1 liability plainly exclude from unlawful combinations or conspiracies the activities of a single firm.

one of its unincorporated divisions.[16] Although this Court has not previously addressed the question,[17] there can be little doubt that the operations of a corporate enterprise organized into divisions must be judged as the conduct of a single actor. The existence of an unincorporated division reflects no more than a firm's decision to adopt an organizational division of labor. A division within a corporate structure pursues the common interests of the whole rather than interests separate from those of the corporation itself; a business enterprise establishes divisions to further its own interests in the most efficient manner. Because coordination between a corporation [467 U.S. 752, 771] and its division does not represent a sudden joining of two independent sources of economic power previously pursuing separate interests, it is not an activity that warrants 1 scrutiny.

Indeed, a rule that punished coordinated conduct simply because a corporation delegated certain responsibilities to autonomous units might well discourage corporations from creating divisions with their presumed benefits. This would serve no useful antitrust purpose but could well deprive consumers of the efficiencies that decentralized management may bring.

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16 See 691 F.2d 310, 316 (CA7 1982) (decision below); Cliff Food Stores, Inc. v. Kroger, Inc., 417 F.2d 203, 205-206 (CA5 1969); Joseph E. Seagram & Sons, Inc. v. Hawaiian Oke & Liquors, Ltd., 416 F.2d 71, 83-84 (CA9 1969), cert. denied, 396 U.S. 1062 (1970); Poller v. Columbia Broadcasting System, Inc., 109 U.S. App. D.C., at 174, 284 F.2d, at 603.

17 The Court left this issue unresolved in Poller v. Columbia Broadcasting System, Inc., 368 U.S., at 469, n. 4.

C

For similar reasons, the coordinated activity of a parent and its wholly owned subsidiary must be viewed as that of a single enterprise for purposes of 1 of the Sherman Act. A parent and its wholly owned subsidiary have a complete unity of interest. Their objectives are common, not disparate; their general corporate actions are guided or determined not by two separate corporate consciousnesses, but one. They are not unlike a multiple team of horses drawing a vehicle under the control of a single driver. With or without a formal "agreement," the subsidiary acts for the benefit of the parent, its sole shareholder. If a parent and a wholly owned subsidiary do "agree" to a course of action, there is no sudden joining of economic resources that had previously served different interests, and there is no justification for 1 scrutiny.

Indeed, the very notion of an "agreement" in Sherman Act terms between a parent and a wholly owned subsidiary lacks meaning. A 1 agreement may be found when "the conspirators had a unity of purpose or a common design and understanding, or a meeting of minds in an unlawful arrangement." American Tobacco Co. v. United States, 328 U.S. 781, 810 (1946). But in reality a parent and a wholly owned subsidiary always have a "unity of purpose or a common design." They share a common purpose whether or not the parent keeps a tight rein over the subsidiary; the parent may assert [467 U.S. 752, 772] full control at any moment if the subsidiary fails to act in the parent's best interests.[18]

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[18] As applied to a wholly owned subsidiary, the so-called "single entity" test is thus inadequate to preserve the Sherman Act's distinction between unilateral and concerted conduct. Followed by the Seventh Circuit below as well as by other Courts of Appeals, this test sets forth various criteria for evaluating

The intra-enterprise conspiracy doctrine looks to the form of an enterprise's structure and ignores the reality Antitrust liability should not depend on whether a corporate subunit is organized as an unincorporated division or a wholly owned subsidiary. A corporation has complete power to maintain a wholly owned subsidiary in either form. The economic, legal, or other considerations that lead corporate management to choose one structure over the other are not relevant to whether the enterprise's conduct seriously threatens competition.[19] Rather, a corporation may adopt the subsidiary form of organization for valid management and related purposes. Separate

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whether a given parent and subsidiary are capable of conspiring with each other. See n. 2, supra; see generally Ogilvie v. Fotomat Corp., 641 F.2d 581 (CA8 1981); Las Vegas Sun, Inc. v. Summa Corp., 610 F.2d 614 (CA9 1979), cert. denied, 447 U.S. 906 (1980); Photovest Corp. v. Fotomat Corp., 606 F.2d 704 (CA7 1979), cert. denied, 445 U.S. 917 (1980). These criteria measure the "separateness" of the subsidiary: whether it has separate control of its day-to-day operations, separate officers, separate corporate headquarters, and so forth. At least when a subsidiary is wholly owned, however, these factors are not sufficient to describe a separate economic entity for purposes of the Sherman Act. The factors simply describe the manner in which the parent chooses to structure a subunit of itself. They cannot overcome the basic fact that the ultimate interests of the subsidiary and the parent are identical, so the parent and the subsidiary must be viewed as a single economic unit.

[19] Because an "agreement" between a parent and its wholly owned subsidiary is no more likely to be anticompetitive than an agreement between two divisions of a single corporation, it does not matter that the parent "availed [itself] of the privilege of doing business through separate corporations," Perma Life Mufflers, Inc. v. International Parts Corp., 392 U.S. 134, 141 (1968). The purposeful choice of a parent corporation to organize a subunit as a subsidiary is not itself a reason to heighten antitrust scrutiny, because it is not laden with anticompetitive risk.

incorporation may improve [467 U.S. 752, 773] management, avoid special tax problems arising from multistate operations, or serve other legitimate interests.[20] Especially in view of the increasing complexity of corporate operations, a business enterprise should be free to structure itself in ways that serve efficiency of control, economy of operations, and other factors dictated by business judgment without increasing its exposure to antitrust liability. Because there is nothing inherently anticompetitive about a corporation's decision to create a subsidiary, the intra-enterprise conspiracy doctrine "impose[s] grave legal consequences upon organizational distinctions that are of de minimis meaning and effect." Sunkist Growers, Inc. v. Winckler & Smith Citrus Products Co., 370 U.S. 19, 29 (1962).[21]

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[20] For example, "[s]eparate incorporation may reduce federal or state taxes or facilitate compliance with regulatory or reporting laws. Local incorporation may also improve local identification. Investors or lenders may prefer to specialize in a particular aspect of a conglomerate's business. Different parts of the business may require different pension or profit-sharing plans or different accounting practices." Areeda, 97 Harv. L. Rev., at 453.

[21] Sunkist Growers provides strong support for the notion that separate incorporation does not necessarily imply a capacity to conspire. The defendants in that case were an agricultural cooperative, its wholly owned subsidiary, and a second cooperative comprising only members of the first. The Court refused to find a 1 or 2 conspiracy among them because they were "one `organization' or `association' even though they have formally organized themselves into three separate legal entities." 370 U.S., at 29. Although this holding derived from statutory immunities granted to agricultural organizations, the reasoning of Sunkist Growers supports the broader principle that substance, not form, should determine whether a separately incorporated entity is capable of conspiring under 1.

If antitrust liability turned on the garb in which a corporate subunit was clothed, parent corporations would be encouraged to convert subsidiaries into unincorporated divisions. Indeed, this is precisely what the Seagram company did after this Court's decision in Kiefer-Stewart Co. v. Joseph E. Seagram & Sons, Inc., 340 U.S. 211 (1951).[22] Such an [467 U.S. 752, 774] incentive serves no valid antitrust goals but merely deprives consumers and producers of the benefits that the subsidiary form may yield.

The error of treating a corporate division differently from a wholly owned subsidiary is readily seen from the facts of this case. Regal was operated as an unincorporated division of Lear Siegler for four years before it became a wholly owned subsidiary of Copperweld. Nothing in this record indicates any meaningful difference between Regal's operations as a division and its later operations as a separate corporation. Certainly nothing suggests that Regal was a greater threat to competition as a subsidiary of Copperweld than as a division of Lear Siegler. Under either arrangement, Regal might have acted to bar a new competitor from entering the market. In one case it could have relied on economic power from other quarters of the Lear Siegler corporation; instead it drew on the strength of its separately incorporated parent, Copperweld. From the standpoint of the antitrust laws, there is no reason to treat one more harshly than the other. As Chief Justice Hughes cautioned,

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22 See Joseph E. Seagram & Sons, Inc. v. Hawaiian Oke & Liquors, Ltd., 416 F.2d 71 (CA9 1969), cert. denied, 396 U.S. 1062 (1970).

"[r]ealities must dominate the judgment." Appalachian Coals, Inc. v. United States, 288 U.S., at 360.[23]

D

Any reading of the Sherman Act that remains true to the Act's distinction between unilateral and concerted conduct will necessarily disappoint those who find that distinction arbitrary. It cannot be denied that 1's focus on concerted [467 U.S. 752, 775] behavior leaves a "gap" in the Act's proscription against unreasonable restraints of trade. See post, at 789. An unreasonable restraint of trade may be effected not only by two independent firms acting in concert; a single firm may restrain trade to precisely the same extent if it alone possesses the combined market power of those same two firms. Because the Sherman Act does not prohibit unreasonable restraints of trade as such - but only restraints effected by a contract, combination, or conspiracy - it leaves untouched a single firm's anticompetitive conduct (short of threatened monopolization) that may be indistinguishable in economic effect from the conduct of two firms subject to 1 liability.

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[23] The dissent argues that references in the legislative history to "trusts" suggest that Congress intended 1 to govern the conduct of all affiliated corporations. See post, at 787-788. But those passages explicitly refer to combinations created for the very purpose of restraining trade. None of the cited debates refers to the postacquisition conduct of corporations whose initial affiliation was lawful. Indeed, Senator Sherman stated:

> "It is the unlawful combination, tested by the rules of common law and human experience, that is aimed at by this bill, and not the lawful and useful combination." 21 Cong. Rec. 2457 (1890).

We have already noted that Congress left this "gap" for eminently sound reasons. Subjecting a single firm's every action to judicial scrutiny for reasonableness would threaten to discourage the competitive enthusiasm that the antitrust laws seek to promote. See supra, at 767-769. Moreover, whatever the wisdom of the distinction, the Act's plain language leaves no doubt that Congress made a purposeful choice to accord different treatment to unilateral and concerted conduct. Had Congress intended to outlaw unreasonable restraints of trade as such, 1's requirement of a contract, combination, or conspiracy would be superfluous, as would the entirety of 2.[24] Indeed, this Court has

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[24] Even if common-law intracorporate conspiracies were firmly established when Congress passed the Sherman Act, the obvious incompatibility of an intracorporate conspiracy with 1 is sufficient to refute the dissent's suggestion that Congress intended to incorporate such a definition. See post, at 784-787. Moreover, it is far from clear that intracorporate conspiracies were recognized at common law in 1890. Even today courts disagree whether corporate employees can conspire with themselves or with the corporation for purposes of certain statutes, such as 42 U.S.C. 1985(3). Compare, e. g., Novotny v. Great Am. Fed. Sav. & Loan Assn., 584 F.2d 1235 (CA3 1978) (en banc), vacated and remanded on other grounds, 442 U.S. 366 (1979), with Dombrowski v. Dowling, 459 F.2d 190 (CA7 1972). And in 1890 it was disputed whether a corporation could itself be guilty of a crime that required criminal intent, such as [467 U.S. 752, 776] conspiracy. Commentators appear to agree that courts began finding corporate liability for such crimes only around the turn of the century. See generally Edgerton, Corporate Criminal Responsibility, 36 Yale L. J. 827, 828, and n. 11 (1927); Miller, Corporate Criminal Liability: A Principle Extended to Its Limits, 38 Fed. Bar J. 49 (1979); Note, 60 Harv. L. Rev. 283, 284, and n. 9 (1946). Of course, Congress changed that common-law rule when it explicitly provided that a corporation could be guilty of a 1 conspiracy. But the point remains that the Sherman Act did not import a pre-existing common-law tradition recognizing conspiracies between corporations and their own employees.

recognized [467 U.S. 752, 776] that 1 is limited to concerted conduct at least since the days of United States v. Colgate & Co., 250 U.S. 300 (1919). Accord, post, at 789.

The appropriate inquiry in this case, therefore, is not whether the coordinated conduct of a parent and its wholly owned subsidiary may ever have anticompetitive effects, as the dissent suggests. Nor is it whether the term "conspiracy" will bear a literal construction that includes parent corporations and their wholly owned subsidiaries. For if these were the proper inquiries, a single firm's conduct would be subject to 1 scrutiny whenever the coordination of two employees was involved. Such a rule would obliterate the Act's distinction between unilateral and concerted conduct, contrary to the clear intent of Congress as interpreted by the weight of judicial authority. See n. 15, supra. Rather, the appropriate inquiry requires us to explain the logic underlying Congress' decision to exempt unilateral conduct from 1 scrutiny, and to assess whether that logic similarly excludes the conduct of a parent and its wholly owned subsidiary. Unless we second-guess the judgment of Congress to limit 1 to concerted conduct, we can only conclude that the coordinated behavior of a parent and its wholly owned subsidiary falls outside the reach of that provision.

Although we recognize that any "gap" the Sherman Act leaves is the sensible result of a purposeful policy decision by Congress, we also note that the size of any such gap is open [467 U.S. 752, 777] to serious question. Any anticompetitive activities of corporations and their wholly owned subsidiaries meriting antitrust remedies may be policed adequately without resort to an intra-enterprise conspiracy doctrine. A corporation's initial acquisition of control will always be subject to scrutiny under 1 of the Sherman Act and 7 of the Clayton Act, 38 Stat. 731, 15 U.S.C. 18. Thereafter, the enterprise is fully subject to 2 of the

Sherman Act and 5 of the Federal Trade Commission Act, 38 Stat. 719, 15 U.S.C. 45. That these statutes are adequate to control dangerous anticompetitive conduct is suggested by the fact that not a single holding of antitrust liability by this Court would today be different in the absence of an intra-enterprise conspiracy doctrine. It is further suggested by the fact that the Federal Government, in its administration of the antitrust laws, no longer accepts the concept that a corporation and its wholly owned subsidiaries can "combine" or "conspire" under 1.[25] Elimination of the intra-enterprise conspiracy doctrine with respect to corporations and their wholly owned subsidiaries will therefore not cripple antitrust enforcement. It will simply eliminate treble damages from private state tort suits masquerading as antitrust actions.

IV

We hold that Copperweld and its wholly owned subsidiary Regal are incapable of conspiring with each other for purposes of 1 of the Sherman Act. To the extent that prior decisions of this Court are to the contrary, they are disapproved and overruled. Accordingly, the judgment of the Court of Appeals is reversed.

It is so ordered. [467 U.S. 752, 778]

JUSTICE WHITE took no part in the consideration or decision of this case.

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25 "[T]he [intra-enterprise conspiracy] doctrine has played a relatively minor role in government enforcement actions, and the government has not relied on the doctrine in recent years." Brief for United States as Amicus Curiae 26, n. 42.

JUSTICE STEVENS, with whom JUSTICE BRENNAN and JUSTICE MARSHALL join, dissenting.

It is safe to assume that corporate affiliates do not vigorously compete with one another. A price-fixing or market-allocation agreement between two or more such corporate entities does not, therefore, eliminate any competition that would otherwise exist. It makes no difference whether such an agreement is labeled a "contract," a "conspiracy," or merely a policy decision, because it surely does not unreasonably restrain competition within the meaning of the Sherman Act. The Rule of Reason has always given the courts adequate latitude to examine the substance rather than the form of an arrangement when answering the question whether collective action has restrained competition within the meaning of 1.

Today the Court announces a new per se rule: a wholly owned subsidiary is incapable of conspiring with its parent under 1 of the Sherman Act. Instead of redefining the word "conspiracy," the Court would be better advised to continue to rely on the Rule of Reason. Precisely because they do not eliminate competition that would otherwise exist but rather enhance the ability to compete, restraints which enable effective integration between a corporate parent and its subsidiary - the type of arrangement the Court is properly concerned with protecting - are not prohibited by 1. Thus, the Court's desire to shield such arrangements from antitrust liability provides no justification for the Court's new rule.

In contrast, the case before us today presents the type of restraint that has precious little to do with effective integration between parent and subsidiary corporations. Rather, the purpose of the challenged conduct was to exclude a potential competitor of the subsidiary from the market. The jury apparently concluded that the two

defendant corporations - [467 U.S. 752, 779] Copperweld and its subsidiary Regal - had successfully delayed Independence's entry into the steel tubing business by applying a form of economic coercion to potential suppliers of financing and capital equipment, as well as to potential customers. Everyone seems to agree that this conduct was tortious as a matter of state law. This type of exclusionary conduct is plainly distinguishable from vertical integration designed to achieve competitive efficiencies. If, as seems to be the case, the challenged conduct was manifestly anticompetitive, it should not be immunized from scrutiny under 1 of the Sherman Act.

I

Repudiation of prior cases is not a step that should be taken lightly. As the Court wrote only days ago: "[A]ny departure from the doctrine of stare decisis demands special justification." Arizona v. Rumsey, ante, at 212. It is therefore appropriate to begin with an examination of the precedents.

In United States v. Yellow Cab Co., 332 U.S. 218 (1947), the Court explicitly stated that a corporate subsidiary could conspire with its parent:

> "The fact that these restraints occur in a setting described by the appellees as a vertically integrated enterprise does not necessarily remove the ban of the Sherman Act. The test of illegality under the Act is the presence or absence of an unreasonable restraint on interstate commerce. Such a restraint may result as readily from a conspiracy among those who are affiliated or integrated under common ownership as from a conspiracy among those who are otherwise independent." Id., at 227.

The majority attempts to explain Yellow Cab by suggesting that it dealt only with unlawful acquisition of subsidiaries. Ante, at 761-762. But the Court mentioned acquisitions only as an additional consideration separate from the passage [467 U.S. 752, 780] quoted above,[1] and more important, the Court explicitly held that restraints imposed by the corporate parent on the affiliates that it already owned in themselves violated 1.[2]

At least three cases involving the motion picture industry also recognize that affiliated corporations may combine or conspire within the meaning of 1. In United States v. Crescent Amusement Co., 323 U.S. 173 (1944), as the Court recognizes, ante, at 762, n. 6, the only conspirators were affiliated corporations. The majority's claim that the case involved only unlawful acquisitions because of the Court's comments concerning divestiture of the affiliates cannot be squared with the passage immediately following that cited by the majority, which states that there had been unlawful conduct going beyond the acquisition of subsidiaries:

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1 The language I have quoted, most of which is overlooked by the majority, makes it clear that the Court's adoption of the concept of conspiracy between affiliated corporations was unqualified. As the first word of the sentence indicates, the Court's following statement: "Similarly, any affiliation or integration flowing from an illegal conspiracy cannot insulate the conspirators from the sanctions which Congress has imposed," *332 U.S., at 227,* expresses a separate if related point.

2 "[B]y preventing the cab operating companies under their control from purchasing cabs from manufacturers other than CCM, the appellees deny those companies the opportunity to purchase cabs in a free, competitive market. The Sherman Act has never been thought to sanction such a conspiracy to restrain the free purchase of goods in interstate commerce." Id., at 226-227 (footnote omitted).

> "That principle is adequate here to justify divestiture of all interest in some of the affiliates since their acquisition was part of the fruits of the conspiracy. But the relief need not, and under these facts should not, be so restricted [to divestiture]. The fact that the companies were affiliated induced joint action and agreement. Common control was one of the instruments in bringing about unity of purpose and unity of action and in making the conspiracy effective. If that affiliation continues, [467 U.S. 752, 781] there will be tempting opportunity for these exhibitors to continue to act in combination against the independents." 323 U.S., at 189 - 190 (emphasis supplied).

Similarly, in Schine Chain Theatres, Inc. v. United States, 334 U.S. 110 (1948), the Court held that concerted action by parents and subsidiaries constituted an unlawful conspiracy.[3] That was also the holding in United States v. Griffith, 334 U.S. 100, 109 (1948). The majority's observation that in these cases there were alternative grounds that could have been used to reach the same result, ante, at 763, n. 8, disguises neither the fact that the holding that actually appears in these opinions rests on conspiracy between affiliated entities, nor that today's holding is inconsistent with what was actually held in these cases.

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[3] "[T]he combining of the open and closed towns for the negotiation of films for the circuit was a restraint of trade and the use of monopoly power in violation of 1 and 2 of the Act. The concerted action of the parent company, its subsidiaries, and the named officers and directors in that endeavor was a conspiracy which was not immunized by reason of the fact that the members were closely affiliated rather than independent. See United States v. Yellow Cab Co., 332 U.S. 218, 227 ; United States v. Crescent Amusement Co., 323 U.S. 173 ." 334 U.S., at 116 .

In Kiefer-Stewart Co. v. Joseph E. Seagram & Sons, Inc., 340 U.S. 211 (1951), the Court's holding was plain and unequivocal:

> "Respondents next suggest that their status as `mere instrumentalities of a single manufacturing-merchandizing unit' makes it impossible for them to have conspired in a manner forbidden by the Sherman Act. But this suggestion runs counter to our past decisions that common ownership and control does not liberate corporations from the impact of the antitrust laws. E. g. United States v. Yellow Cab Co., 332 U.S. 218 . The rule is especially applicable where, as here, respondents hold themselves out as competitors." Id., at 215. [467 U.S. 752, 782]

This holding is so clear that even the Court, which is not wanting for inventiveness in its reading of the prior cases, cannot explain it away. The Court suggests only that today Kiefer-Stewart might be decided on alternative grounds, ante, at 764, ignoring the fact that today's holding is inconsistent with the ground on which the case actually was decided.[4]

A construction of the statute that reaches agreements between corporate parents and subsidiaries was again embraced by the Court in Timken Roller Bearing Co. v.

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[4] In Kiefer-Stewart, Seagram unsuccessfully argued that Yellow Cab was confined to cases concerning unlawful acquisitions, see Brief for Respondents, O. T. 1950, No. 297, p. 21. Thus the Kiefer-Stewart Court considered and rejected exactly the same argument embraced by today's majority.

United States, 341 U.S. 593 (1951),[5] and Perma Life Mufflers, Inc. v. International Parts Corp., 392 U.S. 134 (1968).[6] The majority only notes that there might have been other grounds for decision available in these cases, ante, at 764-766, but again it cannot deny that its new rule is inconsistent with what the Court actually did write in these cases. [467 U.S. 752, 783]

Thus, the rule announced today is inconsistent with what this Court has held on at least seven previous occasions.[7] Perhaps most illuminating is the fact that until

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5 "The fact that there is common ownership or control of the contracting corporations does not liberate them from the impact of the antitrust laws. E. g., Kiefer-Stewart Co. v. Seagram & Sons, [340 U.S.,] at 215. Nor do we find any support in reason or authority for the proposition that agreements between legally separate persons and companies to suppress competition among themselves and others can be justified by labeling the project a `joint venture.' Perhaps every agreement and combination to restrain trade could be so labeled." 341 U.S., at 598 .

6 "There remains for consideration only the Court of Appeals' alternative holding that the Sherman Act claim should be dismissed because respondents were all part of a single business entity and were therefore entitled to cooperate without creating an illegal conspiracy. But since respondents Midas and International availed themselves of the privilege of doing business through separate corporations, the fact of common ownership could not save them from any of the obligations that the law imposes on separate entities. See Timken Co. v. United States, 341 U.S. 593, 598 (1951); United States v. Yellow Cab Co., 332 U.S. 218, 227 (1947)." 392 U.S., at 141 -142.

7 Also pertinent is United States v. Citizens & Southern National Bank, 422 U.S. 86 (1975), in which the Court wrote:

> "The central message of the Sherman Act is that a business entity must find new customers and higher profits through internal expansion - that is,

today, whether they favored the doctrine or not, it had been the universal conclusion of both the lower courts[8] and the commentators[9] that this Court's cases establish that a parent

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> by competing successfully rather than by arranging treaties with its competitors. This Court has held that even commonly owned firms must compete against each other, if they hold themselves out as distinct entities. 'The corporate interrelationships of the conspirators . . . are not determinative of the applicability of the Sherman Act.' United States v. Yellow Cab Co., 332 U.S. 218, 227 . See also Kiefer-Stewart Co. v. Joseph E. Seagram & Sons, Inc., 340 U.S. 211, 215 ; Timken Roller Bearing Co. v. United States, 341 U.S. 593, 598 ; Perma Life Mufflers, Inc. v. International Parts Corp., 392 U.S. 134, 141 -142." Id., at 116-117.

[8] See, e. g., William Inglis & Sons Baking Co. v. ITT Continental Baking Co., 668 F.2d 1014, 1054 (CA9), cert. denied, 459 U.S. 825 (1982); Ogilvie v. Fotomat Corp., 641 F.2d 581, 587-588 (CA8 1981); Las Vegas Sun, Inc. v. Summa Corp., 610 F.2d 614, 617-618 (CA9 1979), cert. denied, 447 U.S. 906 (1980); Photovest Corp. v. Fotomat Corp., 606 F.2d 704, 726 (CA7 1979), cert. denied, 445 U.S. 917 (1980); Columbia Metal Culvert Co. v. Kaiser Aluminum & Chemical Corp., 579 F.2d 20, 33-35, and n. 49 (CA3), cert. denied, 439 U.S. 876 (1978); H & B Equipment Co. v. International Harvester Co., 577 F.2d 239, 244-245 (CA5 1978); George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc., 508 F.2d 547, 557 (CA1 1974), cert. denied, 421 U.S. 1004 (1975).

[9] See, e. g., Report of the Attorney General's National Committee to Study the Antitrust Laws 30-36 (1955) (hereinafter cited as Attorney General's Committee Report); L. Sullivan, Law of Antitrust 114 (1977); Areeda, Intraenterprise Conspiracy in Decline, 97 Harv. L. Rev. 451 (1983); Handler, Through the Antitrust Looking Glass - Twenty-First Annual Antitrust Review, 57 Calif. L. Rev. 182, 182-193 (1969); Handler & Smart, The Present Status of the Intracorporate Conspiracy Doctrine, 3 Cardozo L. Rev. 23, 26-61 (1981); McQuade, Conspiracy, Multicorporate Enterprises, and Section 1 of the Sherman Act, 41 Va. L. Rev. 183,

[467 U.S. 752, 784] and a wholly owned subsidiary corporation are capable of conspiring in violation of 1. In this very case the Court of Appeals observed:

> "[T]he salient factor is that the Supreme Court's decisions, while they need not be read with complete literalism, of course they cannot be ignored. It is no accident that every Court of Appeals to consider the question has concluded that a parent and its subsidiary have the same capacity to conspire, whether or not they can be found to have done so in a particular case." 691 F.2d 310, 317 (CA7 1982) (footnotes omitted).

Thus, we are not writing on a clean slate. "[W]e must bear in mind that considerations of stare decisis weigh heavily in the area of statutory construction, where Congress is free to change this Court's interpretation of its legislation." Illinois Brick Co. v. Illinois, 431 U.S. 720, 736 (1977).[10] There can be no doubt that the Court today changes what has been taken to be the long-settled rule: a rule that

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188-212 (1955); Willis & Pitofsky, Antitrust Consequences of Using Corporate Subsidiaries, 43 N. Y. U. L. Rev. 20, 22-24 (1968); Comment, [467 U.S. 752, 784] Intraenterprise Antitrust Conspiracy: A Decisionmaking Approach, 71 Calif. L. Rev. 1732, 1739-1745 (1983) (hereinafter cited as Comment, Decisionmaking); Comment, All in the Family: When Will Internal Discussions Be Labeled Intra-Enterprise Conspiracy?, 14 Duquesne L. Rev. 63 (1975); Note, "Conspiring Entities" Under Section 1 of the Sherman Act, 95 Harv. L. Rev. 661 (1982); Note, Intra-Enterprise Conspiracy Under Section 1 of the Sherman Act: A Suggested Standard, 75 Mich. L. Rev. 717, 718-727 (1977) (hereinafter cited as Note, Suggested Standard).

[10] See also Monsanto Co. v. Spray-Rite Service Co., 465 U.S. 752, 769 (1984) (BRENNAN, J., concurring).

Congress did not revise at any point in the last four decades. At a minimum there should be a strong presumption against the approach taken today by the Court. It is to the merits of that approach that I now turn.

II

The language of 1 of the Sherman Act is sweeping in its breadth: "Every contract, combination in the form of trust or [467 U.S. 752, 785] otherwise, or conspiracy, in restraint of trade or commerce among the several States, . . . is declared to be illegal." 15 U.S.C. 1. This Court has long recognized that Congress intended this language to have a broad sweep, reaching any form of combination:

> "[I]n view of the many new forms of contracts and combinations which were being evolved from existing economic conditions, it was deemed essential by an all-embracing enumeration to make sure that no form of contract or combination by which an undue restraint of interstate or foreign commerce was brought about could save such restraint from condemnation. The statute under this view evidenced the intent not to restrain the right to make and enforce contracts, whether resulting from combination or otherwise, which did not unduly restrain interstate or foreign commerce, but to protect that commerce from being restrained by methods, whether old or new, which would constitute an interference that is an undue restraint." Standard Oil Co. v. United States, 221 U.S. 1, 59-60 (1911).

This broad construction is illustrated by the Court's refusal to limit the statute to actual agreements. Even mere acquiescence in an anticompetitive scheme has been held sufficient to satisfy the statutory language.[11]

Since the statute was written against the background of the common law,[12] reference to the common law is particularly enlightening in construing the statutory requirement of a "contract, combination in the form of trust or otherwise, or conspiracy." Under the common law, the question whether [467 U.S. 752, 786] affiliated corporations constitute a plurality of actors within the meaning of the statute is easily answered. The well-settled rule is that a corporation is a separate legal entity; the separate corporate form cannot be disregarded.[13] The Congress that passed the Sherman Act was well acquainted with this rule. See 21 Cong. Rec. 2571 (1890) (remarks of Sen. Teller) ("Each corporation is a creature by itself"). Thus it has long been the law of criminal conspiracy that the officers of even a single corporation are capable of conspiring with each other or the

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11 See Albrecht v. Herald Co., 390 U.S. 145, 149 (1968); United States v. Parke, Davis & Co., 362 U.S. 29, 44 (1960). See also Monsanto Co. v. Spray-Rite Service Co., 465 U.S., at 764, n. 9.

12 E. g., Associated General Contractors of California, Inc. v. Carpenters, 459 U.S. 519, 531-532 (1983); National Society of Professional Engineers v. United States, 435 U.S. 679, 687-688 (1978); Standard Oil, 221 U.S., at 59.

13 See, e. g., Schenley Corp. v. United States, 326 U.S. 432, 437 (1946) (per curiam); New Colonial Ice Co. v. Helvering, 292 U.S. 435, 440-442 (1934); Burnet v. Clark, 287 U.S. 410 (1932); Louisville, C. & C. R. Co. v. Letson, 2 How. 497, 558-559 (1844); Bank of the United States v. Deveaux, 5 Cranch 61 (1809).

corporation.[14] This Court has held that a corporation can conspire with its employee,[15] and that a labor union can "combine" with its business agent within the meaning of 1.[16] This concept explains the Timken Court's statement that the affiliated corporations in that case made [467 U.S. 752, 787] "agreements between legally separate persons," 341 U.S., at 598. Thus, today's holding that agreements between parent and subsidiary corporations involve merely unilateral conduct is at odds with the way that this Court has traditionally understood the concept of a combination or conspiracy, and also at odds with the way in which the

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[14] Attorney General's Committee Report, supra n. 9, at 30-31 (citing Barron v. United States, 5 F.2d 799 (CA1 1925); Mininsohn v. United States, 101 F.2d 477 (CA3 1939); Egan v. United States, 137 F.2d 369 (CA8), cert. denied, 320 U.S. 788 (1943)). See also, e. g., United States v. Hartley, 678 F.2d 961, 971-972 (CA11 1982), cert. denied, 459 U.S. 1170 (1983); Alamo Fence Co. of Houston v. United States, 240 F.2d 179 (CA5 1957); Patterson v. United States, 222 F. 599, 618-619 (CA6), cert. denied, 238 U.S. 635 (1915); Union Pacific Coal Co. v. United States, 173 F. 737 (CA8 1909); United States v. Consolidated Coal Co., 424 F. Supp. 577, 579-581 (SD Ohio 1976); United States v. Griffin, 401 F. Supp. 1222, 1224-1225 (SD Ind. 1975), aff'd mem. sub nom. United States v. Metro Management Corp., 541 F.2d 284 (CA7 1976); United States v. Bridell, 180 F. Supp. 268, 273 (ND Ill. 1960); United States v. Kemmel, 160 F. Supp. 718 (MD Pa. 1958); Welling, Intracorporate Plurality in Criminal Conspiracy Law, 33 Hastings L. J. 1155, 1191-1199 (1982).

[15] See Hyde v. United States, 225 U.S. 347, 367-368 (1912). See also United States v. Sampson, 371 U.S. 75 (1962); Fong Foo v. United States, 369 U.S. 141 (1962) (per curiam); Lott v. United States, 367 U.S. 421 (1961); Nye & Nissen v. United States, 336 U.S. 613 (1949).

[16] See Duplex Printing Press Co. v. Deering, 254 U.S. 443, 465 (1921).

Congress that enacted the Sherman Act surely understood it.

Holding that affiliated corporations cannot constitute a plurality of actors is also inconsistent with the objectives of the Sherman Act. Congress was particularly concerned with "trusts," hence it named them in 1 as a specific form of "combination" at which the statute was directed. Yet "trusts" consisted of affiliated corporations. As Senator Sherman explained:

> "Because these combinations are always in many States and, as the Senator from Missouri says, it will be very easy for them to make a corporation within a State. So they can; but that is only one corporation of the combination. The combination is always of two or more, and in one case of forty-odd corporations, all bound together by a link which holds them under the name of trustees, who are themselves incorporated under the laws of one of the States." 21 Cong. Rec. 2569 (1890).

The activities of these "combinations" of affiliated corporations were of special concern:

> "[A]ssociated enterprise and capital are not satisfied with partnerships and corporations competing with each other, and have invented a new form of combination commonly called trusts, that seeks to avoid competition by combining the controlling corporations, partnerships, and individuals engaged in the same business, and placing the power and property of the combination under the government of a few individuals,

> and often under the control of a single man called a trustee, a chairman, or a president. [467 U.S. 752, 788]
>
> "The sole object of such a combination is to make competition impossible. It can control the market, raise or lower prices, as will best promote its selfish interests, reduce prices in a particular locality and break down competition and advance prices at will where competition does not exist. Its governing motive is to increase the profits of the parties composing it. The law of selfishness, uncontrolled by competition, compels it to disregard the interest of the consumer. It dictates terms to transportation companies, it commands the price of labor without fear of strikes, for in its field it allows no competitors. . . . It is this kind of a combination we have to deal with now." Id., at 2457.[17]

Thus, the corporate subsidiary, when used as a device to eliminate competition, was one of the chief evils to

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[17] See also 21 Cong. Rec. 2562 (1890) (remarks of Sen. Teller); id., at 2570 (remarks of Sen. Sherman); id., at 2609 (remarks of Sen. Morgan).

which the Sherman Act was addressed.[18] The anomaly in today's holding is that the corporate devices most similar to the original "trusts" are now those which free an enterprise from antitrust scrutiny. [467 U.S. 752, 789]

III

The Court's reason for rejecting the concept of a combination or conspiracy among a parent corporation and its wholly owned subsidiary is that it elevates form over substance - while in form the two corporations are separate legal entities, in substance they are a single integrated enterprise and hence cannot comprise the plurality of actors necessary to satisfy 1. Ante, at 771-774. In many situations the Court's reasoning is perfectly sensible, for the affiliation of corporate entities often is procompetitive precisely because, as the Court explains, it enhances efficiency. A challenge to conduct that is merely an incident of the desirable integration that accompanies such affiliation should fail. However, the protection of such conduct

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[18] This legislative history thus demonstrates the error in the majority's conclusion that only acquisitions of corporate affiliates fall within 1. See ante, at 761-762. The conduct of the trusts that Senator Sherman and others objected to went much further than mere acquisitions. Indeed, the irony of the Court's approach is that, had it been adopted in 1890, it would have meant that 1 would have no application to trust combinations which had already been formed - the very trusts to which Senator Sherman was referring.

I cannot believe that the Court really intends to express doubt as to whether the Congress that passed the Sherman Act thought conspiracy doctrine could apply to corporations. Ante, at 775-776, n. 24. If that were not the case, then the Sherman Act would have no application to corporations. Since, as is clear and as the Court concedes, the Sherman Act does apply to corporations, there can be no doubt that Congress intended to apply the law of conspiracy to agreements between corporations.

provides no justification for the Court's new rule, precisely because such conduct cannot be characterized as an unreasonable restraint of trade violative of 1. Conversely, the problem with the Court's new rule is that it leaves a significant gap in the enforcement of 1 with respect to anticompetitive conduct that is entirely unrelated to the efficiencies associated with integration.

Since at least United States v. Colgate & Co., 250 U.S. 300 (1919), 1 has been construed to require a plurality of actors. This requirement, however, is a consequence of the plain statutory language, not of any economic principle. As an economic matter, what is critical is the presence of market power, rather than a plurality of actors.[19] From a competitive standpoint, a decision of a single firm possessing power to reduce output and raise prices above competitive levels has the same consequence as a decision by two firms acting together who have acquired an equivalent amount of market [467 U.S. 752, 790] power through an agreement not to compete.[20] Unilateral conduct

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19 Market power is the ability to raise prices above those that would be charged in a competitive market. See Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 27 , n. 46 (1984); United States Steel Corp. v. Fortner Enterprises, Inc., 429 U.S. 610, 620 (1977); United States v. E. I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956).

20 Significantly, the Court never suggests that the plurality-of-actors requirement has any intrinsic economic significance. Rather, it suggests that the requirement has evidentiary significance: combinations are more likely to signal anticompetitive conduct than is unilateral activity: "In any conspiracy, two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit. This not only reduces the diverse directions in which economic power is aimed but suddenly increases the economic power moving in one particular direction." Ante, at 769. That is true, but it is also true of any ordinary commercial contract

by a firm with market power has no less anticompetitive potential than conduct by a plurality of actors which generates or exploits the same power,[21] and probably more, since the unilateral actor avoids the policing problems faced by cartels.

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between separate entities, as can be seen if one substitutes the word "contract" for "conspiracy" in the passage I have quoted. The language of the Sherman Act indicates that it treats "contracts" and "conspiracies" as equivalent concepts - both satisfy the multiplicity-of-actors requirement - and yet one of the most fundamental points in antitrust jurisprudence, dating at least to Standard Oil, is that there is nothing inherently anticompetitive about a contract. Similarly, an agreement to act "for common benefit" in itself is unremarkable - all agreements are in some sense a restraint of trade be they contracts or conspiracies. It is only when trade is unreasonably restrained that 1 is implicated. The Court's evidentiary concern lacks merit.

[21] We made this point in the context of resale price maintenance in United States v. Parke, Davis & Co., 362 U.S. 29 (1960):

> "The Sherman Act forbids combinations of traders to suppress competition. True, there results the same economic effect as is accomplished by a prohibited combination to suppress price competition if each customer, although induced to do so solely by a manufacturer's announced policy, independently decides to observe specified resale prices. So long as Colgate is not overruled, this result is tolerated but only when it is the consequence of a mere refusal to sell in the exercise of a manufacturer's right `freely to exercise his own independent discretion as to parties with whom he will deal.'" Id., at 44 (quoting Colgate, 250 U.S., at 307).

The rule of Yellow Cab thus has an economic justification. It addresses a gap in antitrust enforcement by reaching anticompetitive agreements between affiliated corporations which [467 U.S. 752, 791] have sufficient market power to restrain marketwide competition, but not sufficient power to be considered monopolists within the ambit of 2 of the Act.[22] The doctrine is also useful when a third party declines to join a conspiracy to restrain trade among affiliated corporations, and is harmed as a result through a boycott or similar tactics designed to penalize the refusal. In such cases, since there has been no agreement with the third party, only an agreement between the affiliated corporations can be the basis for 1 inquiry.[23] Finally, it must be remembered that not all persons who

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22 "[I]t is the potential which this conspiracy concept holds for the development of a rational enforcement policy which, if anything, will ultimately attract the courts. If conduct of a single corporation which restrains trade were to violate Section 1, a forceful weapon would be available to the government with which to challenge conduct which in oligopolistic industries creates or reinforces entry barriers. Excessive advertising in the cereal, drug, or detergent industries, annual style changes in the auto industry, and other such practices could be reached as soon as they threatened to inhibit competition; there would be no need to wait until a `dangerous probability' of monopoly had been reached, the requirement under Section 2 `attempt' doctrine. Nor would a single firm restraint of trade rule be overbroad. It would in no way threaten single firm activity - setting a price, deciding what market it would deal in, or the like - which did not threaten competitive conditions." L. Sullivan, supra n. 9, 114, at 324 (footnotes omitted).

23 This was the case in Kiefer-Stewart, for example. Seagram had refused to sell liquor to Kiefer-Stewart unless it agreed to an illegal resale price maintenance scheme. Kiefer-Stewart refused to agree, and as a result was injured by losing access to Seagram's products. See 340 U.S., at 213 .

restrain trade wear grey flannel suits. Businesses controlled by organized crime often attempt to gain control of an industry through violence or intimidation of competitors; in such cases 1 can be applied to separately incorporated businesses which benefit from such tactics, but which may be ultimately controlled by a single criminal enterprise.[24] [467 U.S. 752, 792]

The rule of Yellow Cab and its progeny is not one that condemns every parent-subsidiary relationship. A single firm, no matter what its corporate structure may be, is not expected to compete with itself.[25] Functional integration

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[24] See United States v. Turkette, 452 U.S. 576, 588 -593 (1981) (discussing congressional findings underlying the Organized Crime Control Act of 1970). Section 1 of the Sherman Act has on occasion been used against [467 U.S. 752, 792] various types of racketeering activity. See Hartwell, Criminal RICO and Antitrust, 52 Antitrust L. J. 311, 312-313 (1983); McLaren, Antitrust and Competition - Review of the Past Year and Suggestions for the Future, in New York State Bar Assn., 1971 Antitrust Law Symposium 1, 3 (1971).

[25] See Comment, Decisionmaking, supra n. 9, at 1753-1757; Note, Suggested Standard, supra n. 9, at 735-738. Professor Sullivan elaborates:

> "Picture, at one end of the spectrum, a family business which operates one retail store in each of three or four adjacent communities. All of the stores are managed as a unit by one individual, the founder of the business who sets policy, does all the buying, decides on all the advertising, sets prices, and hires and fires all employees other than family members. The fact that each store is operated by a separate corporation should not convert a family business into a cartel . . . . If there is, as a practical matter, an integrated ownership and management, this small business is a single firm. And a single firm cannot compete with itself.

by its very nature requires unified action; hence in itself it has never been sufficient to establish the existence of an unreasonable restraint of trade: "In discussing the charge in the Yellow Cab case, we said that the fact that the conspirators were integrated did not insulate them from the act, not that corporate integration violated the act." United States v. Columbia Steel Co., 334 U.S. 495, 522 (1948). Restraints that act only on the parent or its subsidiary as a consequence of an otherwise lawful integration do not violate 1 of the Sherman Act.[26] But if the behavior at issue is unrelated to any functional integration between the affiliated corporations and [467 U.S. 752, 793] imposes a restraint on third parties of sufficient magnitude to restrain marketwide competition, as a matter of economic substance, as well as form, it is appropriate to characterize the conduct as a "combination or conspiracy in restraint of trade."[27]

Hence it cannot restrain price competition with itself, or divide markets with itself, or act as a common purchasing agent for itself or otherwise restrain competition with itself, regardless of how many separate corporations the single firm may, for reasons unrelated to the act, be divided into." L. Sullivan, supra n. 9, 114, at 326-327.

[26] Thus, the Court is wrong to suggest, ante, at 771-772, 774-776, and n. 24, that Yellow Cab could reach truly unilateral conduct involving only the employees of a single firm.

[27] If the rule of Yellow Cab and its progeny could be easily circumvented through, for example, use of unincorporated divisions instead of subsidiaries, then there would be reason to question its efficacy as a tool for rational antitrust enforcement. However, the Court is incorrect when it asserts, ante, at 770-771, 772-774, that there is no economic substance in a distinction between unincorporated divisions, which cannot provide a plurality of actors, and wholly owned subsidiaries, which under Yellow Cab can. If that were the case, incorporated subsidiaries

For example, in Yellow Cab the Court read the complaint as alleging that integration had assisted the parent in excluding competing manufacturers from the marketplace, 332 U.S., at 226 -227, leading the Court to conclude that "restraint of interstate trade was not only effected by the combination of the appellees but was the primary object of the combination." Id., at 227. Similarly, in Crescent Amusement the Court noted that corporate affiliation between exhibitors enhanced their buying power and "was one of the instruments in . . . making the conspiracy effective" in excluding independents from the market. 323 U.S., at 189 -190. Thus, in both cases the Court found that the affiliation enhanced the ability of the parent corporation to exclude the competition of third parties, and hence raised entry [467 U.S. 752, 794] barriers faced by actual and potential competitors. When conduct restrains trade not merely by integrating affiliated corporations but rather by restraining the ability of others to compete, that conduct has competitive significance drastically different from procompetitive integration.[28] In these cases, the

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would never be used to achieve integration - the ready availability of an unincorporated alternative would always be employed in order to avoid antitrust liability. The answer is provided by the Court itself - the use of subsidiaries often makes possible operating efficiencies that are unavailable through the use of unincorporated divisions. Ante, at 772-774. We may confidently assume that any corporate parent whose contingent antitrust liability exceeds the savings it realizes through the use of subsidiaries already utilizes unincorporated divisions instead of corporate subsidiaries. Thus, it is more than merely a question of form when a decision is made to use corporate subsidiaries instead of unincorporated divisions, and the rule is not that easily circumvented.

[28] See L. Sullivan, supra n. 9, 114, at 328 ("To have two competitors acting concertedly two separate firms, not just persons, are needed. Thus `concerted action' by two `legal persons' which is limited solely to the internal management of a single firm

affiliation assisted exclusionary conduct; it was not the competitive equivalent of unilateral integration but instead generated power to restrain marketwide competition.

There are other ways in which corporate affiliation can operate to restrain competition. A wholly owned subsidiary might market a "fighting brand" or engage in other predatory behavior that would be more effective if its ownership were concealed than if it was known that only one firm was involved. A predator might be willing to accept the risk of bankrupting a subsidiary when it could not afford to let a division incur similar risks. Affiliated corporations might enhance their power over suppliers by agreeing to refuse to deal with those who deal with an

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does not restrain competition; but `concerted action' by two `legal persons' which erects barriers to entry by another separate firm, a competitor or potential competitor, can be a restraint of trade"); see also Willis & Pitofsky, supra n. 9, at 38-41. The Attorney General's National Committee to Study the Antitrust Laws made the same point in 1955:

> "The substance of the Supreme Court decisions is that concerted action between a parent and subsidiary or between subsidiaries which has for its purpose or effect coercion or unreasonable restraint on the trade of strangers to those acting in concert is prohibited by Section 1. Nothing in these opinions should be interpreted as justifying the conclusion that concerted action solely between a parent and subsidiary or subsidiaries, the purpose and effect of which is not coercive restraint of the trade of strangers to the corporate family, violates Section 1. Where such concerted action restrains no trade and is designed to restrain no trade other than that of the parent and its subsidiaries, Section 1 is not violated." Attorney General's Committee Report, supra n. 9, at 34.

actual or potential competitor [467 U.S. 752, 795] of one of them; such a threat might be more potent coming from both corporations than from only one.[29]

In this case, it may be that notices to potential suppliers of respondent emanating from Copperweld carried more weight than would notices coming only from Regal. There was evidence suggesting that Regal and Copperweld were not integrated, and that the challenged agreement had little to do with achieving procompetitive efficiencies and much to do with protecting Regal's market position. The Court does not even try to explain why their common ownership meant that Copperweld and Regal were merely obtaining benefits associated with the efficiencies of integration. Both the District Court and the Court of

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29 Professor Sullivan provides another example:

> "[P]icture a parent corporation and its wholly owned subsidiary (or two corporations wholly owned by the same parent or stockholder group) which operate, respectively, a newspaper and a radio station in the same city. If the radio station, which has no local competitors, were to deny advertising to a local business because the latter advertised in a rival newspaper, the integration between the two corporations, however close in terms of ownership or management or both, would not protect them from a charge of conspiracy to restrain trade . . . [T]he concerted action here involved is not merely carrying on the business of a single integrated firm, it is action which is aimed at restraining trade by utilizing such market power as is possessed by the firm because of its radio station in order to erect a competitive barrier in front of a competitor of the firm's newspaper." L. Sullivan, supra n. 9, 114, at 327 (footnote omitted).

Appeals thought that their agreement had a very different result - that it raised barriers to entry and imposed an appreciable marketwide restraint. The Court's discussion of the justifications for corporate affiliation is therefore entirely abstract - while it dutifully lists the procompetitive justifications for corporate affiliation, ante, at 772-774, it fails to explain how any of them relate to the conduct at issue in this case. What is challenged here is not the fact of integration between Regal and Copperweld, but their specific agreement with respect to Independence. That agreement concerned the exclusion of [467 U.S. 752, 796] Independence from the market, and not any efficiency resulting from integration. The facts of this very case belie the conclusion that affiliated corporations are incapable of engaging in the kind of conduct that threatens marketwide competition. The Court does not even attempt to assess the competitive significance of the conduct under challenge here - it never tests its economic assumptions against the concrete facts before it. Use of economic theory without reference to the competitive impact of the particular economic arrangement at issue is properly criticized when it produces overly broad per se rules of antitrust liability;[30] criticism is not less warranted when a per se rule of antitrust immunity is adopted in the same way.

In sum, the question that the Court should ask is not why a wholly owned subsidiary should be treated differently from a corporate division, since the immunity accorded that type of arrangement is a necessary consequence of Colgate. Rather the question should be why two corporations that engage in a predatory course of conduct which produces a marketwide restraint on competition and which, as separate legal entities, can be easily fit within the language of 1, should be immunized

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30 E. g., Continental T. V., Inc. v. GTE Sylvania Inc., 433 U.S. 36 (1977). [467 U.S. 752, 797]

from liability because they are controlled by the same godfather. That is a question the Court simply fails to confront. I respectfully dissent.

U.S. Supreme Court

ALLIED TUBE & CONDUIT CORP. v. INDIAN HEAD, INC., 486 U.S. 492 (1988)

486 U.S. 492
ALLIED TUBE & CONDUIT CORP. v. INDIAN HEAD, INC.
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

No. 87-157

OPINION

Argued February 24, 1988
Decided June 13, 1988

The National Fire Protection Association - a private organization that includes members representing industry, labor, academia, insurers, organized medicine, firefighters, and government - sets and publishes product standards and codes related to fire protection. Its National Electrical Code (Code), which establishes requirements for the design and installation of electrical wiring systems, is routinely adopted into law by a substantial number of state and local governments, and is widely adopted as setting acceptable standards by private product-certification laboratories, insurance underwriters, and electrical inspectors, contractors, and distributors. Throughout the relevant period, the Code permitted the use of electrical conduit made of steel. Respondent, a manufacturer of plastic conduit, initiated a proposal before the Association to extend Code approval to plastic conduit as well. The proposal was approved by one of the Association's professional panels, and thus could be adopted into the Code by a simple majority of the members attending the Association's 1980 annual meeting. Before the meeting was

held, petitioner, the Nation's largest producer of steel conduit, members of the steel industry, other steel conduit manufacturers, and independent sales agents collectively agreed to exclude respondent's product from the 1981 Code by packing the annual meeting with new Association members whose only function was to vote against respondent's proposal. After the proposal was defeated at the meeting and an appeal to the Association's Board of Directors was denied, respondent brought suit in Federal District Court, alleging that petitioner and others had unreasonably restrained trade in the electrical conduit market in violation of 1 of the Sherman Act. The jury found petitioner liable, but the court granted a judgment n.o.v. for petitioner, reasoning that it was entitled to antitrust immunity under the doctrine of Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 . The Court of Appeals reversed.

Held: Noerr antitrust immunity does not apply to petitioner. Pp. 499-510.

(a) The scope of Noerr protection depends on the source, context, and nature of the anticompetitive restraint at issue. Where a restraint is the result of valid governmental action, as opposed to private action, [486 U.S. 492, 493] those urging the governmental action enjoy absolute immunity from antitrust liability for the anticompetitive restraint. In this case, the relevant context is the standard-setting process of a private association without official authority that includes members having horizontal and vertical business relations and economic incentives to restrain competition. Such an association cannot be treated as a "quasi-legislative" body simply because legislatures routinely adopt its Code, and thus petitioner does not enjoy the

immunity afforded those who merely urge the government to restrain trade. Pp. 499-502.

(b) Nor does Noerr immunity apply to petitioner on the theory that the exclusion of plastic conduit from the Code, and the effect that exclusion had of its own force in the marketplace, were incidental to a valid effort to influence governmental action. Although, because a large number of governments routinely adopt the Code into law, efforts to influence the Association's standard-setting process are arguably the most effective means of influencing legislation regulating electrical conduit, and although Noerr immunity is not limited to "direct" petitioning of government officials, the Noerr doctrine does not immunize every concerted activity that is genuinely intended to influence governmental action. There is no merit to the argument that, regardless of the Association's nonlegislative status, petitioner's efforts to influence the Association must be given the same wide berth accorded legislative lobbying or efforts to influence legislative action in the political arena. Pp. 502-504.

(c) Unlike the publicity campaign to influence legislation in Noerr, petitioner's activity did not take place in the open political arena, where partisanship is the hallmark of decisionmaking, but took place within the confines of a private standard-setting process. The validity of petitioner's efforts to influence the Code is not established, without more, by petitioner's literal compliance with the Association's rules, for the hope of the Code's procompetitive benefits depends upon the existence of safeguards sufficient to prevent the standard-setting process from being biased by members with economic interests in restraining competition. An

association cannot validate the anticompetitive activities of its members simply by adopting rules that fail to provide such safeguards. At least where, as here, an economically interested party exercises decisionmaking authority in formulating a product standard for a private association that comprises market participants, that party enjoys no Noerr immunity from any antitrust liability flowing from the effect the standard has of its own force in the marketplace. Pp. 505-510.

817 F.2d 938, affirmed.

BRENNAN, J., delivered the opinion of the Court, in which REHNQUIST, C. J., and MARSHALL, BLACKMUN, STEVENS, SCALIA, and KENNEDY, JJ., [486 U.S. 492, 494] joined. WHITE, J., filed a dissenting opinion, in which O'CONNOR, J., joined, post, p. 511.

Marvin E. Frankel argued the cause for petitioner. With him on the briefs were Robert M. Heller, Arthur B. Kramer, and Debora K. Grobman.

Fredric W. Yerman argued the cause for respondent. With him on the brief were Michael Malina, Randolph S. Sherman, and Richard A. De Sevo. *

Briefs of amici curiae urging reversal were filed for the State of Illinois by Neil F. Hartigan, Attorney General, and Robert E. Davy, Jr., Assistant Attorney General; and for the Western Fire Chiefs Association et al. by William J. Meeske and Alexander D. Thomson.

Briefs of amici curiae urging affirmance were filed for the United States et al. by Solicitor General Fried, Assistant Attorney General Rule, Deputy Solicitor General Cohen, Deputy Assistant Attorney General Starling, Paul J.

Larkin, Jr., Robert B. Nicholson, John J. Powers III, Marion L. Jetton, Robert D. Paul, and Ernest J. Isenstadt; and for the State of Alaska et al. by Robert Abrams, Attorney General of New York, O. Peter Sherwood, Solicitor General, and Lloyd E. Constantine, Susan Beth Farmer, Elizabeth M. O'Neill, and George W. Sampson, Assistant Attorneys General, Grace Berg Schaible, Attorney General of Alaska, Richard D. Monkmon, Assistant Attorney General, Robert K. Corbin, Attorney General of Arizona, John Steven Clark, Attorney General of Arkansas, Jeffrey A. Bell, Deputy Attorney General, John Van de Kamp, Attorney General of California, Andrea Ordin, Chief Assistant Attorney General, Thomas P. Dove, Deputy Attorney General, Duane Woodard, Attorney General of Colorado, Thomas P. McMahon, First Assistant Attorney General, Joseph I. Lieberman, Attorney General of Connecticut, Robert M. Langer, Assistant Attorney General, Warren Price III, Attorney General of Hawaii, Robert A. Marks, Supervising Deputy Attorney General, Thomas J. Miller, Attorney General of Iowa, John Perkins, Deputy Attorney General, James E. Tierney, Attorney General, of Maine, Stephen L. Wessler, Assistant Attorney General, J. Joseph Curran, Jr., Attorney General of Maryland, Michael F. Brockmeyer, Assistant Attorney General, Frank J. Kelley, Attorney General of Michigan, Louis J. Caruso, Solicitor General, Robert C. Ard, Jr., Assistant Attorney General, Hubert H. Humphrey III, Attorney General of Minnesota, Cary Edwards, Attorney General of New Jersey, Laurel A. Price, Deputy Attorney General, Lacy H. Thornburg, Attorney General of North Carolina, Richard H. Carlton, Assistant Attorney General, Anthony J. Celebrezze, Jr., Attorney General of Ohio, Dave [486 U.S. 492, 495] Frohnmayer, Attorney General of Oregon, LeRoy S. Zimmerman, Attorney General of Pennsylvania, Eugene F. Wayne, Chief Deputy Attorney General, James E. O'Neil, Attorney General of Rhode Island, Roger A. Tellinghuisen, Attorney General of South Dakota, Jim Mattox, Attorney General of Texas, Mary F. Keller, Executive Assistant

Attorney General, John J. White, Assistant Attorney General, David L. Wilkinson, Attorney General of Utah, Kenneth O. Eikenberry, Attorney General of Washington, John R. Ellis, Deputy Attorney General, Tina Kondo, Assistant Attorney General, Charles G. Brown, Attorney General of West Virginia, Mark D. Kindt, Deputy Attorney General, Donald J. Hanaway, Attorney General of Wisconsin, and Kevin J. O'Connor, Assistant Attorney General. [486 U.S. 492, 495]

JUSTICE BRENNAN delivered the opinion of the Court.

Petitioner contends that its efforts to affect the product standard-setting process of a private association are immune from antitrust liability under the Noerr doctrine primarily because the association's standards are widely adopted into law by state and local governments. Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961) (Noerr). The United States Court of Appeals for the Second Circuit held that Noerr immunity did not apply. We affirm.

I

The National Fire Protection Association (Association) is a private, voluntary organization with more than 31,500 individual and group members representing industry, labor, academia, insurers, organized medicine, firefighters, and government. The Association, among other things, publishes product standards and codes related to fire protection through a process known as "consensus standard making." One of the codes it publishes is the National Electrical Code (Code), which establishes product and performance requirements for the design and installation of electrical wiring systems. Revised every three years, the Code is the most influential electrical code in the nation. A substantial number of state and local governments routinely

adopt the Code into law with little or no change; private certification laboratories, such as Underwriters Laboratories, normally will not list and label [486 U.S. 492, 496] an electrical product that does not meet Code standards; many underwriters will refuse to insure structures that are not built in conformity with the Code; and many electrical inspectors, contractors, and distributors will not use a product that falls outside the Code.

Among the electrical products covered by the Code is electrical conduit, the hollow tubing used as a raceway to carry electrical wires through the walls and floors of buildings. Throughout the relevant period, the Code permitted using electrical conduit made of steel, and almost all conduit sold was in fact steel conduit. Starting in 1980, respondent began to offer plastic conduit made of polyvinyl chloride. Respondent claims its plastic conduit offers significant competitive advantages over steel conduit, including pliability, lower installed cost, and lower susceptibility to short circuiting. In 1980, however, there was also a scientific basis for concern that, during fires in high-rise buildings, polyvinyl chloride conduit might burn and emit toxic fumes.

Respondent initiated a proposal to include polyvinyl chloride conduit as an approved type of electrical conduit in the 1981 edition of the Code. Following approval by one of the Association's professional panels, this proposal was scheduled for consideration at the 1980 annual meeting, where it could be adopted or rejected by a simple majority of the members present. Alarmed that, if approved, respondent's product might pose a competitive threat to steel conduit, petitioner, the Nation's largest producer of steel conduit, met to plan strategy with, among others, members of the steel industry, other steel conduit manufacturers, and its independent sales agents. They collectively agreed to exclude respondent's product from the

1981 Code by packing the upcoming annual meeting with new Association members whose only function would be to vote against the polyvinyl chloride proposal.

Combined, the steel interests recruited 230 persons to join the Association and to attend the annual meeting to [486 U.S. 492, 497] vote against the proposal. Petitioner alone recruited 155 persons - including employees, executives, sales agents, the agents' employees, employees from two divisions that did not sell electrical products, and the wife of a national sales director. Petitioner and the other steel interests also paid over $100,000 for the membership, registration, and attendance expenses of these voters. At the annual meeting, the steel group voters were instructed where to sit and how and when to vote by group leaders who used walkie-talkies and hand signals to facilitate communication. Few of the steel group voters had any of the technical documentation necessary to follow the meeting. None of them spoke at the meeting to give their reasons for opposing the proposal to approve polyvinyl chloride conduit. Nonetheless, with their solid vote in opposition, the proposal was rejected and returned to committee by a vote of 394 to 390. Respondent appealed the membership's vote to the Association's Board of Directors, but the Board denied the appeal on the ground that, although the Association's rules had been circumvented, they had not been violated.[1]

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[1] Respondent also sought a tentative interim amendment to the Code, but that was denied on the ground that there was not sufficient exigency to merit an interim amendment. The Association subsequently approved use of polyvinyl chloride conduit for buildings of less than three stories in the 1984 Code, and for all buildings in the 1987 Code.

In October 1981, respondent brought this suit in Federal District Court, alleging that petitioner and others had unreasonably restrained trade in the electrical conduit market in violation of 1 of the Sherman Act. 26 Stat. 209, 15 U.S.C. 1. A bifurcated jury trial began in March 1985. Petitioner conceded that it had conspired with the other steel interests to exclude respondent's product from the Code and that it had a pecuniary interest to do so. The jury, instructed under the rule of reason that respondent carried the burden of showing that the anticompetitive effects of petitioner's actions outweighed any procompetitive benefits of standard [486 U.S. 492, 498] setting, found petitioner liable. In answers to special interrogatories, the jury found that petitioner did not violate any rules of the Association and acted, at least in part, based on a genuine belief that plastic conduit was unsafe, but that petitioner nonetheless did "subvert" the consensus standardmaking process of the Association. App. 23-24. The jury also made special findings that petitioner's actions had an adverse impact on competition, were not the least restrictive means of expressing petitioner's opposition to the use of polyvinyl chloride conduit in the marketplace, and unreasonably restrained trade in violation of the antitrust laws. The jury then awarded respondent damages, to be trebled, of $3.8 million for lost profits resulting from the effect that excluding polyvinyl chloride conduit from the 1981 Code had of its own force in the marketplace. No damages were awarded for injuries stemming from the adoption of the 1981 Code by governmental entities.[2]

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[2] Although the District Court was of the view that at trial respondent relied solely on the theory that its injury "flowed from legislative action," App. to Pet. for Cert. 31a, the Court of Appeals determined that respondent was awarded damages only on the theory "that the stigma of not obtaining [Code] approval of its products and [petitioner's] `marketing' of that stigma caused independent marketplace harm to [respondent] in those

The District Court then granted a judgment n.o.v. for petitioner, reasoning that Noerr immunity applied because the Association was "akin to a legislature" and because petitioner, "by the use of methods consistent with acceptable standards of political action, genuinely intended to influence the [Association] with respect to the National Electrical Code, and to thereby influence the various state and local legislative bodies which adopt the [Code]." App. to Pet. for [486 U.S. 492, 499] Cert. 28a, 30a. The Court of Appeals reversed, rejecting both the argument that the Association should be treated as a "quasi-legislative" body because legislatures routinely adopt the Code and the argument that efforts to influence the Code were immune under Noerr as indirect attempts to influence state and local governments. 817 F.2d 938 (1987). We granted certiorari to address important issues regarding the application of Noerr immunity to private standard-setting associations.[3] 484 U.S. 814 (1987).

II

Concerted efforts to restrain or monopolize trade by petitioning government officials are protected from antitrust liability under the doctrine established by Noerr; Mine

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jurisdictions permitting use of [polyvinyl chloride] conduit, as well as those which later adopted the 1984 [Code], which permitted use of [polyvinyl chloride] conduit in buildings less than three stories high. [Respondent] did not seek redress for any injury arising from the adoption of the [Code] by the various governments." 817 F.2d 938, 941, n. 3 (1987) (emphasis added). We decide the case as it was framed by the Court of Appeals.

[3] We also granted certiorari on the issue whether, if not immune under Noerr, petitioner's conduct violated the Sherman Act, but we now vacate our grant of that issue as improvident.

Workers v. Pennington, 381 U.S. 657, 669 -672 (1965); and California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508 (1972). The scope of this protection depends, however, on the source, context, and nature of the anticompetitive restraint at issue. "[W]here a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action," those urging the governmental action enjoy absolute immunity from antitrust liability for the anticompetitive restraint. Noerr, 365 U.S., at 136 ; see also Pennington, supra, at 671. In addition, where, independent of any government action, the anticompetitive restraint results directly from private action, the restraint cannot form the basis for antitrust liability if it is "incidental" to a valid effort to influence governmental action. Noerr, supra, at 143. The validity of such efforts, and thus the applicability of Noerr immunity, varies with the context and nature of the activity. A publicity campaign directed at the general public, seeking legislation or executive action, enjoys antitrust immunity even when the campaign employs unethical [486 U.S. 492, 500] and deceptive methods. Noerr, supra, at 140-141. But in less political arenas, unethical and deceptive practices can constitute abuses of administrative or judicial processes that may result in antitrust violations.[4] California Motor Transport, supra, at 512-513.

In this case, the restraint of trade on which liability was predicated was the Association's exclusion of respondent's product from the Code, and no damages were imposed for the incorporation of that Code by any government. The relevant context is thus the standard-setting process of a private association. Typically, private

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4 Of course, in whatever forum, private action that is not genuinely aimed at procuring favorable government action is a mere sham that cannot be deemed a valid effort to influence government action. Noerr, 365 U.S., at 144 ; California Motor Transport, 404 U.S., at 511 .

standard-setting associations, like the Association in this case, include members having horizontal and vertical business relations. See generally 7 P. Areeda, Antitrust Law ¶ 1477, p. 343 (1986) (trade and standard-setting associations routinely treated as continuing conspiracies of their members). There is no doubt that the members of such associations often have economic incentives to restrain competition and that the product standards set by such associations have a serious potential for anticompetitive harm.[5] See American Society of Mechanical Engineers, Inc. v. Hydrolevel Corp., 456 U.S. 556, 571 (1982). Agreement on a product standard is, after all, implicitly an agreement not to manufacture, distribute, or purchase certain types of products. Accordingly, private standard-setting associations have traditionally been objects of antitrust scrutiny. See, e. g., ibid.; Radiant Burners, Inc. v. Peoples Gas Light & Coke Co., 364 U.S. 656 (1961) (per curiam). See also FTC v. Indiana Federation of Dentists, [486 U.S. 492, 501] 476 U.S. 447 (1986). When, however, private associations promulgate safety standards based on the merits of objective expert judgments and through procedures that prevent the standard-setting process from being biased by members with economic interests in stifling product competition, cf. Hydrolevel, supra, at 570-573 (noting absence of "meaningful safeguards"), those private standards can have significant procompetitive advantages. It is this potential for procompetitive benefits that has led most lower courts to

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5 "Product standardization might impair competition in several ways. . . . [It] might deprive some consumers of a desired product, eliminate quality competition, exclude rival producers, or facilitate oligopolistic pricing by easing rivals' ability to monitor each other's prices." 7 P. Areeda, Antitrust Law § 1503, p. 373 (1986).

apply rule-of-reason analysis to product standard-setting by private associations.[6]

Given this context, petitioner does not enjoy the immunity accorded those who merely urge the government to restrain trade. We agree with the Court of Appeals that the Association cannot be treated as a "quasi-legislative" body simply because legislatures routinely adopt the Code the Association publishes. 817 F.2d, at 943-944. Whatever de facto authority the Association enjoys, no official authority has been conferred on it by any government, and the decisionmaking body of the Association is composed, at least in part, of persons with economic incentives to restrain trade. See Continental Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 707 -708 (1962). See also id., at 706-707; Goldfarb v. Virginia State Bar, 421 U.S. 773, 791 -792 (1975). "We may presume, absent a showing to the contrary, that [a government] acts in the public interest. A private party, on the other hand, may be presumed to be acting primarily on his or its own behalf." Hallie v. Eau Claire, 471 U.S. 34, 45 (1985). The dividing line between restraints resulting from governmental action and those resulting from private action

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[6] See 2 J. von Kalinowski, Antitrust Laws and Trade Regulation 61.013., 61.03, 61.04, pp. 61-6 to 61-7, 61-18 to 61-29 (1981) (collecting cases). Concerted efforts to enforce (rather than just agree upon) private product standards face more rigorous antitrust scrutiny. See Radiant Burners, Inc. v. Peoples Gas Light & Coke Co., 364 U.S. 656, 659 -660 (1961) (per curiam). See also Fashion Originators' Guild of America, Inc. v. FTC, 312 U.S. 457 (1941).

[486 U.S. 492, 502] may not always be obvious.[7] But where, as here, the restraint is imposed by persons unaccountable to the public and without official authority, many of whom have personal financial interests in restraining competition, we have no difficulty concluding that the restraint has resulted from private action.

Noerr immunity might still apply, however, if, as petitioner argues, the exclusion of polyvinyl chloride conduit from the Code, and the effect that exclusion had of its own force in the marketplace, were incidental to a valid effort to influence governmental action. Petitioner notes that the lion's share of the anticompetitive effect in this case came from the predictable adoption of the Code into law by a large number of state and local governments. See 817 F.2d, at 939, n. 1. Indeed, petitioner argues that, because state and local governments rely so heavily on the Code and lack the resources or technical expertise to second-guess it, efforts to influence the Association's standard-setting process are the most effective means of influencing legislation regulating electrical conduit. This claim to Noerr immunity has some force. The effort to influence governmental action in this case certainly cannot be characterized as a sham given the actual adoption of the 1981 Code into a number of statutes and local ordinances. Nor can we quarrel with petitioner's

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[7] See, e. g., California Motor Transport, supra, at 513 (stating in dicta that "[c]onspiracy with a licensing authority to eliminate a competitor" or "bribery of a public purchasing agent" may violate the antitrust laws); Mine Workers v. Pennington, 381 U.S. 657, 671, and n. 4 (1965) (holding that immunity applied but noting that the trade restraint at issue "was the act of a public official who is not claimed to be a co-conspirator" and contrasting Continental Ore); Continental Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 707-708 (1962); 1 P. Areeda & D. Turner, Antitrust Law ¶ 206 (1978) (discussing the extent to which Noerr immunity should apply to commercial transactions involving the government). See also Goldfarb v. Virginia State Bar, 421 U.S. 773, 791-792 (1975); Continental Ore, supra, at 706-707.

contention that, given the widespread adoption of the Code into [486 U.S. 492, 503] law, any effect the 1981 Code had in the marketplace of its own force was, in the main, incidental to petitioner's genuine effort to influence governmental action.[8] And, as petitioner persuasively argues, the claim of Noerr immunity cannot be dismissed on the ground that the conduct at issue involved no "direct" petitioning of government officials, for Noerr itself immunized a form of "indirect" petitioning. See Noerr (immunizing a publicity campaign directed at the general public on the ground that it was part of an effort to influence legislative and executive action).

Nonetheless, the validity of petitioner's actions remains an issue. We cannot agree with petitioner's absolutist position that the Noerr doctrine immunizes every concerted effort that is genuinely intended to influence governmental action. If all such conduct were immunized then, for example, competitors would be free to enter into horizontal price agreements as long as they wished to propose that price as an appropriate level for governmental ratemaking or price supports. But see Georgia v. Pennsylvania R. Co., 324 U.S. 439, 456 -463 (1945). Horizontal conspiracies or boycotts designed to exact higher prices or other economic advantages from the government would be immunized on the ground that they are genuinely intended to influence the government to agree to the

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[8] The effect, independent of government action, that the 1981 Code had in the marketplace may to some extent have been exacerbated by petitioner's efforts to "market" the stigma respondent's product suffered by being excluded from the Code. See 817 F.2d, at 941, n. 3. Given our disposition infra, we need not decide whether, or to what extent, these "marketing" efforts alter the incidental status of the resulting anticompetitive harm. See generally Noerr, 365 U.S., at 142 (noting that in that case there were. "no specific findings that the railroads attempted directly to persuade anyone not to deal with the truckers").

conspirators' terms. But see Georgia v. Evans, 316 U.S. 159 (1942). Firms could claim immunity for boycotts or horizontal output restrictions on the ground that they are intended to dramatize the plight of their industry and spur legislative action. Immunity might even be [486 U.S. 492, 504] claimed for anticompetitive mergers on the theory that they give the merging corporations added political clout. Nor is it necessarily dispositive that packing the Association's meeting may have been the most effective means of securing government action, for one could imagine situations where the most effective means of influencing government officials is bribery, and we have never suggested that that kind of attempt to influence the government merits protection. We thus conclude that the Noerr immunity of anticompetitive activity intended to influence the government depends not only on its impact, but also on the context and nature of the activity.

Here petitioner's actions took place within the context of the standard-setting process of a private association. Having concluded that the Association is not a "quasi-legislative" body, we reject petitioner's argument that any efforts to influence the Association must be treated as efforts to influence a "quasi-legislature" and given the same wide berth accorded legislative lobbying. That rounding up supporters is an acceptable and constitutionally protected method of influencing elections does not mean that rounding up economically interested persons to set private standards must also be protected. Nor do we agree with petitioner's contention that, regardless of the Association's nonlegislative status, the effort to influence the Code should receive the same wide latitude given ethically dubious efforts to influence legislative action in the political arena, see Noerr, 365 U.S., at 140-141, simply because the ultimate aim of the effort to influence the private standard-setting process was (principally) legislative action. The ultimate aim is not dispositive. A misrepresentation to a court would not

necessarily be entitled to the same antitrust immunity allowed deceptive practices in the political arena simply because the odds were very good that the court's decision would be codified - nor for that matter would misrepresentations made under oath at a legislative committee hearing in the hopes of spurring legislative action. [486 U.S. 492, 505]

What distinguishes this case from Noerr and its progeny is that the context and nature of petitioner's activity make it the type of commercial activity that has traditionally had its validity determined by the antitrust laws themselves. True, in Noerr we immunized conduct that could be characterized as a conspiracy among railroads to destroy business relations between truckers and their customers. Noerr, supra, at 142. But we noted there:

> "There are no specific findings that the railroads attempted directly to persuade anyone not to deal with the truckers. Moreover, all the evidence in the record, both oral and documentary, deals with the railroads' efforts to influence the passage and enforcement of laws. Circulars, speeches, newspaper articles, editorials, magazine articles, memoranda and all other documents discuss in one way or another the railroads' charges that heavy trucks injure the roads, violate the laws and create traffic hazards, and urge that truckers should be forced to pay a fair share of the costs of rebuilding the roads, that they should be compelled to obey the laws, and that limits should be placed upon the weight of the loads they are permitted to carry." 365 U.S., at 142 -143.

In light of those findings, we characterized the railroads' activity as a classic "attempt . . . to influence legislation by a campaign of publicity," an "inevitable" and "incidental" effect of which was "the infliction of some direct injury upon the interests of the party against whom the campaign is directed." Id., at 143. The essential character of such a publicity campaign was, we concluded, political, and could not be segregated from the activity's impact on business. Rather, the plaintiff's cause of action simply embraced the inherent possibility in such political fights "that one group or the other will get hurt by the arguments that are made." Id., at 144. As a political activity, special factors counseled against regulating the publicity campaign under the antitrust laws: [486 U.S. 492, 506]

> "Insofar as [the Sherman] Act sets up a code of ethics at all, it is a code that condemns trade restraints, not political activity, and, as we have already pointed out, a publicity campaign to influence governmental action falls clearly into the category of political activity. The proscriptions of the Act, tailored as they are for the business world, are not at all appropriate for application in the political arena. Congress has traditionally exercised extreme caution in legislating with respect to problems relating to the conduct of political activities, a caution which has been reflected in the decisions of this Court interpreting such legislation. All of this caution would go for naught if we permitted an extension of the Sherman Act to regulate activities of that nature simply because those activities have a commercial impact and involve conduct that can be termed unethical." Id., at 140-141 (footnote omitted).

In Noerr, then, the political context and nature of the activity precluded inquiry into its antitrust validity.[9]

Here the context and nature of the activity do not counsel against inquiry into its validity. Unlike the publicity campaign in Noerr, the activity at issue here did not take place in the open political arena, where partisanship is the hallmark of decisionmaking, but within the confines of a private standard-setting process. The validity of conduct within that process has long been defined and circumscribed by the antitrust laws without regard to whether the private standards are likely to be adopted into law. See supra, at 500. Indeed, because private standard-setting by associations comprising firms with horizontal and vertical business relations is permitted at all under the antitrust laws only on the [486 U.S. 492, 507] understanding that it will be conducted in a nonpartisan manner offering procompetitive benefits, see ibid., the standards of conduct in this context are, at least in some respects, more rigorous than the standards of conduct prevailing in the partisan political arena or in the adversarial process of adjudication. The activity at issue here thus cannot, as in Noerr, be characterized as an activity that has traditionally been regulated with extreme caution, see Noerr, 365 U.S., at 141, or as an activity that "bear[s] little if any resemblance to the combinations normally held violative of the Sherman Act," id., at 136. And petitioner did not confine itself to efforts to persuade an independent decisionmaker, cf. id., at 138, 139 (describing the immunized conduct as "mere solicitation"); rather, it organized and orchestrated the actual exercise of the Association's decisionmaking authority in setting a standard. Nor can the setting of the Association's Code be

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[9] Similarly in California Motor Transport any antitrust review of the validity of the activity at issue was limited and structured by the fact that there the antitrust defendants were "us[ing] the channels and procedures of state and federal agencies and courts." 404 U.S., at 511; see also id., at 512-513.

characterized as merely an exercise of the power of persuasion, for it in part involves the exercise of market power. The Association's members, after all, include consumers, distributors, and manufacturers of electrical conduit, and any agreement to exclude polyvinyl chloride conduit from the Code is in part an implicit agreement not to trade in that type of electrical conduit. Cf. id., at 136. Although one could reason backwards from the legislative impact of the Code to the conclusion that the conduct at issue here is "political," we think that, given the context and nature of the conduct, it can more aptly be characterized as commercial activity with a political impact. Just as the antitrust laws should not regulate political activities "simply because those activities have a commercial impact," id., at 141, so the antitrust laws should not necessarily immunize what are in essence commercial activities simply because they have a political impact.[10] [486 U.S. 492, 508]

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[10] It is admittedly difficult to draw the precise lines separating anticompetitive political activity that is immunized despite its commercial impact from anticompetitive commercial activity that is unprotected despite [486 U.S. 492, 508] its political impact, and this is itself a case close to the line. For that reason we caution that our decision today depends on the context and nature of the activity. Although criticizing the uncertainty of such a particularized inquiry, post, at 513, the dissent does not dispute that the types of activity we describe supra, at 503-504, could not be immune under Noerr and fails to offer an intelligible alternative for distinguishing those nonimmune activities from the activity at issue in this case. Rather, the dissent states without elaboration that the sham exception "is enough to guard against flagrant abuse," post, at 516, apparently embracing the conclusion of the United States Court of Appeals for the Ninth Circuit that the sham exception covers the activity of a defendant who "genuinely seeks to achieve his governmental result, but does so through improper means." Sessions Tank Liners, Inc. v. Joor Mfg., Inc., 827 F.2d 458, 465, n. 5 (1987) (emphasis in original). Such a use of the word "sham" distorts its meaning and bears little relation to the

NAACP v. Claiborne Hardware Co., 458 U.S. 886 (1982), is not to the contrary. In that case we held that the First Amendment protected the nonviolent elements of a boycott of white merchants organized by the National Association for the Advancement of Colored People and designed to make white government and business leaders comply with a list of demands for equality and racial justice. Although the boycotters intended to inflict economic injury on the merchants, the boycott was not motivated by any desire to lessen competition or to reap economic benefits but by the aim of vindicating rights of equality and freedom lying at the heart of the Constitution, and the boycotters were consumers who did not stand to profit financially from a lessening of competition in the boycotted market. Id., at 914-915. Here, in contrast, [486 U.S. 492, 509] petitioner was at least partially motivated by the desire to lessen competition, and, because of petitioner's line of business,

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sham exception Noerr described to cover activity that was not genuinely intended to influence governmental action. 365 U.S., at 144 . See also P. Areeda & H. Hovenkamp, Antitrust Law □ 203.1a, pp. 13-14 (Supp. 1987). More importantly, the Ninth Circuit's approach renders "sham" no more than a label courts could apply to activity they deem unworthy of antitrust immunity (probably based on unarticulated consideration of the nature and context of the activity), thus providing a certain superficial certainty but no real "intelligible guidance" to courts or litigants. Post, at 513. Indeed, the Ninth Circuit concluded that the very activity the dissent deems protected was an unprotected "sham." 827 F.2d, at 465.

stood to reap substantial economic benefits from making it difficult for respondent to compete.[11]

Thus in this case the context and nature of petitioner's efforts to influence the Code persuade us that the validity of those efforts must, despite their political impact, be evaluated under the standards of conduct set forth by the antitrust laws that govern the private standard-setting process. The antitrust validity of these efforts is not established, without more, by petitioner's literal compliance with the rules of the Association, for the hope of procompetitive benefits depends upon the existence of safeguards sufficient to prevent the standard-setting process from being biased by members with economic interests in restraining competition. An association cannot validate the anticompetitive activities of its members simply by adopting rules that fail to provide such safeguards.[12] The issue of immunity in this case thus collapses into the issue of antitrust liability. Although we do not here set forth the rules of antitrust liability governing the private standard-

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[11] Although the absence of such anticompetitive motives and incentives is relevant to determining whether petitioner's restraint of trade is protected under Claiborne Hardware, we do not suggest that the absence of anticompetitive purpose is necessary for Noerr immunity. As the dissent points out, in Noerr itself the major purpose of the activity at issue was anticompetitive. Post, at 512-513. Our statement that the "ultimate aim" of petitioner "is not dispositive," supra, at 504, stands only for the proposition that, at least outside the political context, the mere fact that an anticompetitive activity is also intended to influence governmental action is not alone sufficient to render that activity immune from antitrust liability.

[12] Even petitioner's counsel concedes, for example, that Noerr would not apply if the Association had a rule giving the steel conduit manufacturers a veto over changes in the Code. Tr. of Oral Arg. 41-42.

setting process, we hold that at least where, as here, an economically interested party exercises decisionmaking authority in formulating a product standard for a private association that comprises market participants, that [486 U.S. 492, 510] party enjoys no Noerr immunity from any antitrust liability flowing from the effect the standard has of its own force in the marketplace.

This conclusion does not deprive state and local governments of input and information from interested individuals or organizations or leave petitioner without ample means to petition those governments. Cf. Noerr, 365 U.S., at 137 -138. See also California Motor Transport, 404 U.S., at 510 . Petitioner, and others concerned about the safety or competitive threat of polyvinyl chloride conduit, can, with full antitrust immunity, engage in concerted efforts to influence those governments through direct lobbying, publicity campaigns, and other traditional avenues of political expression. To the extent state and local governments are more difficult to persuade through these other avenues, that no doubt reflects their preference for and confidence in the nonpartisan consensus process that petitioner has undermined. Petitioner remains free to take advantage of the forum provided by the standard-setting process by presenting and vigorously arguing accurate scientific evidence before a nonpartisan private standard-

setting body.[13] And petitioner can avoid the strictures of the private standard-setting process by attempting to influence legislatures through other forums. [486 U.S. 492, 511] What petitioner may not do (without exposing itself to possible antitrust liability for direct injuries) is bias the process by, as in this case, stacking the private standard-setting body with decisionmakers sharing their economic interest in restraining competition.

The judgment of the Court of Appeals is

Affirmed.

JUSTICE WHITE, with whom JUSTICE O'CONNOR joins, dissenting.

Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961), held that the Sherman Act should not be construed to forbid joint efforts by railway companies seeking legislation that would disadvantage the trucking industry. These efforts for the

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[13] The dissent mistakenly asserts that we today hold that Noerr immunity does not apply to mere efforts to persuade others to exclude a competitor's product from a private code. See post, at 514-516. Our holding is expressly limited to cases where an "economically interested party exercises decisionmaking authority in formulating a product standard for a private association that comprises market participants." Supra, at 509 (emphasis added); see also supra, at 506-507 (relying in part on the distinction between activity involving the exercise of decisionmaking authority and market power and activity involving mere attempts to persuade an independent decisionmaker). Cf. Noerr, 365 U.S., at 136 . The dissent also mistakenly asserts that this description encompasses all private standard-setting associations. See post, at 515. In fact, many such associations are composed of members with expertise but no economic interest in suppressing competition. See, e. g., Sessions, supra, at 461, and n. 2.

most part involved a public relations campaign rather than direct lobbying of the lawmakers and were held not subject to antitrust challenge because of the fundamental importance of maintaining the free flow of information to the government and the right of the people to seek legislative relief, directly or indirectly. Mine Workers v. Pennington, 381 U.S. 657 (1965), and California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508 (1972), applied the rule to efforts to seek executive action and to administrative and adjudicative proceedings.

The Court now refuses to apply the rule of these cases to the participants in those private organizations, such as the National Fire Protection Association (NFPA), that regularly propound and publish health and safety standards for a variety of products and industries and then present these codes to state and local authorities for the purpose of having them enacted into law. The NFPA and those participating in the code-writing process will now be subject to antitrust liability if their efforts have anticompetitive effects and do not withstand scrutiny under the rule of reason. Believing that this result is a misapplication of the Noerr decision and an improvident construction of the Sherman Act, I respectfully dissent. [486 U.S. 492, 512]

This case presents an even stronger argument for immunity than did Noerr itself. That decision turned on whether the design or purpose of the conduct was to obtain or influence the passage or enforcement of laws. The Court concedes that petitioner's actions in this case constituted a "genuine effort to influence governmental action," ante, at 503, and that this was its "ultimate aim," ante, at 504. In Noerr, the publicity campaign was dispersed widely among the public in a broad but necessary diluted attempt to move public opinion in hopes that government officials would take note and respond accordingly. The campaign apparently had some influence on the passage of tax laws

and other legislation favorable to the railroads in New Jersey, New York, and Ohio, and procured the Governor's veto of a bill that had been passed in Pennsylvania. See 365 U.S., at 130; see also 155 F. Supp. 768, 777-801 (ED Pa. 1957). Here, the NFPA actually drafted proposed legislation in the form of the National Electrical Code (NEC) and presented it countrywide. Not only were petitioner's efforts in this case designed to influence the passage of state laws, but there was also a much greater likelihood that they would be successful than was the case in Noerr. This is germane because it establishes a much greater likelihood that the "purpose" and "design" of petitioner's actions in this case was the "solicitation of governmental action with respect to the passage and enforcement of laws," 365 U.S., at 138.

Rather than directly confronting the severe damage that today's decision does to the Noerr doctrine, the majority asserts that the "ultimate aim" of petitioner's efforts "is not dispositive." Ante, at 504. That statement cannot be reconciled with the statements quoted earlier from Noerr, where it was held that even if one of the major purposes, or even the sole purpose, of the publicity campaign was "to destroy the truckers as competitors," 365 U.S., at 138, those actions were immunized from antitrust liability because ultimately they were "directed toward obtaining governmental action," [486 U.S. 492, 513] id., at 140. The majority later doubles back on this statement, and suggests that it is important in this case that "petitioner was at least partially motivated by the desire to lessen competition, and . . . stood to reap substantial economic benefits from making it difficult for respondent to compete." Ante, at 509. It need hardly be said that all of this was also true in Noerr. Nobody condones fraud, bribery, or misrepresentation in any form, and other state and federal laws ensure that such conduct is punishable. But the point here is that conduct otherwise punishable under the antitrust laws either becomes immune from the operation of those laws when it

is part of a larger design to influence the passage and enforcement of laws, or it does not. No workable boundaries to the Noerr doctrine are established by declaring, and then repeating at every turn, that everything depends on "the context and nature of" the activity, ante, at 504, 505, 506, 509, if we are unable to offer any further guidance about what this vague reference is supposed to mean, especially when the result here is so clearly wrong as long as Noerr itself is reputed to remain good law. One unfortunate consequence of today's decision, therefore, is that district courts and courts of appeals will be obliged to puzzle over claims raised under the doctrine without any intelligible guidance about when and why to apply it.

If there were no private code-writing organizations, and state legislatures themselves held the necessary hearing and wrote codes from scratch, then business concerns like Allied, together with their friends, could jointly testify with impunity about the safety of various products, even though they had anticompetitive motives in doing so. This much the majority concedes, as it does that the major purpose of the code-writing organizations is to influence legislative action. These days it is almost a foregone conclusion that the vast majority of the States will adopt these codes with little or no change. It is untenable to consider the code-writing process by such organizations as the NFPA as too far removed [486 U.S. 492, 514] from the legislative process to warrant application of the doctrine announced in Noerr and faithfully applied in other cases. This was the view of Judge Sneed and his colleagues on the Ninth Circuit in Sessions Tank Liners, Inc. v. Joor Mfg., Inc., 827 F.2d 458 (1987), and the reasons they gave for applying Noerr in this context are much more persuasive than anything to the contrary the majority now has to offer.

The Court's decision is unfortunate for another reason. There are now over 400 private organizations preparing and publishing an enormous variety of codes and standards. State and local governments necessarily, and as a matter of course, turn to these proposed codes in the process of legislating to further the health and safety of their citizens. The code that is at issue in this case, for example, was adopted verbatim by 25 States and the District of Columbia; 19 others adopted it with only minor changes. It is the most widely disseminated and adopted model code in the world today. There is no doubt that the work of these private organizations contributes enormously to the public interest and that participation in their work by those who have the technical competence and experience to do so should not be discouraged.

The Court's decision today will surely do just that. It must inevitably be the case that codes such as the NEC will set standards that some products cannot satisfy and hence in the name of health and safety will reduce or prevent competition, as was the case here. Yet, putative competitors of the producer of such products will now think twice before urging in the course of the code-making process that those products not be approved; for if they are successful (or even if they are not), they may well become antitrust defendants facing treble-damages liability unless they can prove to a court and a jury that they had no evil motives but were merely "presenting and vigorously arguing accurate scientific evidence before a nonpartisan private standard-setting body," ante, at 510 (though with the knowing and inevitable result of eliminating competition). In this case, for example, even [486 U.S. 492, 515] if Allied had not resorted to the tactics it employed, but had done no more than successfully argue in good faith the hazards of using respondent's products, it would have inflicted the same damage on respondent and would have risked facing the

same antitrust suit, with a jury ultimately deciding the health and safety implications of the products at issue.

The Court's suggestion that its decision will not affect the ability of these organizations to assist state and local governments is surely wrong. The Court's holding is "that at least where, as here, an economically interested party exercises decisionmaking authority in formulating a product standard for a private association that comprises market participants, that party enjoys no Noerr immunity from any antitrust liability flowing from the effects the standard has of its own force in the marketplace." Ante, at 509-510. This description encompasses the structure and work of all such organizations as we now know them. The Court is saying, in effect, that where a private organization sets standards, the participants can be sued under the antitrust laws for any effects those standards have in the marketplace other than those flowing from their adoption into law. But the standards will have some effect in the marketplace even where they are also adopted into law, through publicity and other means, thus exposing the participants to liability. Henceforth, therefore, any private organization offers such standards at its peril, and without any of the breathing room enjoyed by other participants in the political process.

The alternative apparently envisioned by the Court is that an organization can gain the protection of the Noerr doctrine as long as nobody with any economic interest in the product is permitted to "exercis[e] decisionmaking authority" (i. e., vote) on its recommendations as to particular product standards. Insisting that organizations like the NFPA conduct themselves like courts of law will have perverse effects. Legislatures are willing to rely on such organizations precisely because their standards are being set by those who [486 U.S. 492, 516] possess an expert understanding of the products and their uses, which are

primarily if not entirely those who design, manufacture, sell, and distribute them. Sanitizing such bodies by discouraging the active participation of those with economic interests in the subject matter undermines their utility.

I fear that exposing organizations like the NFPA to antitrust liability will impair their usefulness by inhibiting frank and open discussion of the health and safety characteristics of new or old products that will be affected by their codes. The Court focuses on the tactics of petitioner that are thought to have subverted the entire process. But it is not suggested that if there are abuses, they are anything more than occasional happenings. The Court does speculate about the terrible practices that applying Noerr in this context could lead us to condone in future cases, ante, at 503-504, but these are no more than fantasies, since nothing of the sort occurred in the wake of Noerr itself. It seems to me that today's decision is therefore an unfortunate case of overkill.

Of course, the Noerr immunity is not unlimited and by its terms is unavailable where the alleged efforts to influence legislation are nothing but a sham. As the Ninth Circuit held, this limitation is enough to guard against flagrant abuse. In any event, occasional abuse is insufficient ground to render the entire process less useful and reliable. I would reverse the judgment below and remand for further proceedings. [486 U.S. 492, 517]

895 F.2d 352
58 USLW 2505, 1990-1 Trade Case P 68,917
(Cite as: 895 F.2d 352)

United States Court of Appeals,
Seventh Circuit.

Dr. Chester A. WILK, D.C., Dr. James W. Bryden, D.C., Dr. Patricia B. Arthur, D.C., and Dr. Michael D. Pedigo, D.C., Plaintiffs-Appellees, Cross-Appellants,

v.

AMERICAN MEDICAL ASSOCIATION, Defendant-Appellant, Cross-Appellee.

Dr. Chester A. WILK, D.C., Dr. James W. Bryden, D.C., Dr. Patricia B. Arthur, D.C., and Dr. Michael D. Pedigo, D.C., Plaintiffs-Appellees, Cross-Appellants,

v.

AMERICAN MEDICAL ASSOCIATION, Joint Commission on Accreditation of Hospitals, American College of Physicians and American Academy of Orthopaedic Surgeons, Defendants-Cross-Appellees.

Nos. 87-2672, 87-2777.

Argued Dec. 1, 1988.
Decided Feb. 7, 1990.
Rehearing and Rehearing En Banc Denied in No. 87-2672 April 25, 1990.

Chirpractors brought antitrust action against, inter alia, national medical association, hospital accreditation association, and national physicians' association. On remand, 719 F.2d 207, the United States District Court for the Northern District of Illinois, Susan Getzendanner, J., 671 F. Supp. 1465, held that national medical association had

engaged in illegal restraint of trade for which injunctive relief was warranted. On appeal, the Court of Appeals, Manion, Circuit Judge, held that: (1) evidence supported finding that national medical association had engaged in illegal boycott against chiropractors; (2) injunctive relief was warranted; and (3) evidence supported finding that neither hospital accreditation association or national physicians' association were liable.

Affirmed.

Before WOOD, Jr., RIPPLE, and MANION, Circuit Judges.

MANION, Circuit Judge.

The district court held that the American Medical Association ("AMA") violated § 1 of the Sherman Act, 15 U.S.C. § 1, by conducting an illegal boycott in restraint of trade directed at chiropractors generally, and the four plaintiffs in particular. The court granted an injunction under § 16 of the Clayton Act, 15 U.S.C. § 26, requiring, among other things, wide publication of its order. The court held that two additional defendants, the Joint Commission on Accreditation of Hospitals ("JCAH"), and the American College of Physicians ("ACP"), had acted independently of the AMA's boycott, and dismissed them from the case. *Wilk v. American Medical Association*, 671 F. Supp. 1465 (N.D.Ill.1987). The AMA appeals the finding of liability, and contends that, in any event, injunctive relief is unnecessary. Plaintiffs cross-appeal against JCAH and ACP. We affirm.

I.

We have observed before that "antitrust cases are notoriously extended." *Ball Memorial Hospital Inc. v. Mutual Hospital Insurance Inc.*, 784 F.2d 1325, 1333 (7th Cir. 1986).

This case is no exception. Plaintiffs Chester A. Wilk, James W. Bryden, Patricia B. Arthur, and Michael D. Pedigo, are licensed chiropractors. Their complaint, originally filed in 1976, charged several defendants with violating §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. It sought both damages and an injunction. (For a list of all the original defendants, see 671 F. Supp. At 1469-70. We discuss here only those relevant to this appeal.) At the first trial, plaintiffs' primary claim was that the defendants engaged in a conspiracy to eliminate the chiropractic profession by refusing to deal with plaintiffs and other chiropractors. Defendants accomplished this, plaintiffs claimed, by using former Principle 3 of the AMA's Principles of Medical Ethics, which prohibited medical physicians from associating professionally with unscientific practitioners. [FN1] Plaintiffs contended that the AMA used Principle 3 to boycott chiropractors by labeling them "unscientific practitioners," and then advising its members, among others, that it was unethical for medical physicians to associate with chiropractors. According to the plaintiffs, the other defendants joined the AMA's boycott.

FN1. Former Principle 3 provided:

> A physician should practice a method of healing founded on a scientific basis; and he should not voluntarily associate with anyone who violates this principle.

A jury returned a verdict for the defendants. An earlier panel of this court, however, reversed that judgment. *Wilk v. American Medical Association*, 719 F.2d 207 (7th Cir. 1983) (*Wilk I*). In reversing and ordering a new trial, we held that, in applying the rule of reason, the jury had been allowed to consider factors beyond the effect of the AMA's conduct on competition. The district court had improperly failed to confine the jury's consideration to the "patient care motive

as contrasted with [the] generalized public interest motive." *Id.* at 229.

Just before the 1987 retrial, plaintiffs abandoned their damages claim and sought only injunctive relief. This shifted the case's focus from the past to the present regarding whether plaintiffs were entitled to an injunction under § 16 of the Clayton Act. After a lengthy bench trial, the district court concluded that the AMA, through former Principle 3, had unreasonably restrained trade in violation of § 1 of the Sherman Act. Because the district court adequately detailed the rather lengthy and complex facts of this case, we only briefly summarize them here. (The facts relevant to the claims against JCAH and ACP are set out in section IV of this opinion regarding plaintiffs' cross-appeal.)

In 1963 the AMA formed its Committee on Quackery ("Committee"). The Committee worked diligently to eliminate chiropractic. A primary method to achieve this goal was to make it unethical for medical physicians to professionally associate with chiropractors. Under former Principle 3, it was unethical for medical physicians to associate with "unscientific practitioners." In 1966, the AMA's House of Delegates passed a resolution labelling chiropractic an unscientific cult.

The district court found the AMA's purpose in all of this was to prevent medical physicians from referring patients to chiropractors and from accepting referrals of patients from chiropractors, so as to prevent chiropractors from obtaining access to hospital diagnostic services and membership on hospital medical staffs, to prevent medical physicians from teaching at chiropractic colleges or engaging in any joint research, and to prevent any cooperation between the two groups in the delivery of health care services. Despite the Committee's efforts, chiropractic ultimately became licensed in all 50 states.

In 1977, the AMA's Judicial Council (now known as the Council on Judicial and Ethical Affairs, although we will use its previous name, as did the district court) adopted new opinions which permitted medical physicians to refer patients to chiropractors, as long as the physicians were confident that the services would be performed according to accepted scientific standards. In 1979, the AMA's House of Delegates begrudgingly adopted Report UU, stating that some things chiropractors did were not without therapeutic value; but even so, it stopped short of saying that these services were based on scientific standards. In 1980, the AMA revised its Principles of Medical Ethics, eliminating Principle 3. With this gesture, the district court found, the AMA's boycott ended. 671 F. Supp. at 1477. (We discuss plaintiffs' contention that the boycott continued until 1983 in the section addressing their cross-appeal against JCAH.)

At trial, the AMA raised the so-called "patient care defense" which this court had formulated in its earlier opinion in this case. *Wilk I*, 719 F.2d at 227. That defense required the AMA generally to show that it acted because of a genuine, and reasonable, concern for scientific method in patient care and that it could not adequately satisfy this concern in a way that was less restrictive of competition. The district court rejected the defense. The court found the AMA failed to establish that throughout the relevant period (1966-1980) their concern for scientific methods in patient care had been objectively reasonable. The court also found the AMA similarly failed to show it could not adequately have satisfied its concern for scientific method in patient care in a manner less restrictive of competition than a nationwide conspiracy to eliminate a licensed profession. 671 F. Supp. at 1481-84.

The AMA settled three antitrust lawsuits in 1978, 1980, and 1986 brought by chiropractors, stipulating and agreeing that under the Judicial Council's current opinions, a medical physician could, without fear of discipline or sanction by the AMA, refer a patient to a licensed chiropractor when the physician believed that such a referral would benefit the patient. Similarly, physicians could also choose to accept or decline patients sent to them by chiropractors. The AMA also confirmed that physicians could teach at chiropractic colleges or seminars.

The AMA's present position regarding chiropractic is that it is ethical for a medical physician to professionally associate with chiropractors, if the physician believes that the association is in his patient's best interests. The district court found that the AMA had not previously communicated this position to its membership.

Based on these findings, the court held that the AMA and its members violated § 1 of the Sherman Act by unlawfully conspiring to restrain trade. According to the court, the AMA's boycott's purpose had been to eliminate chiropractic; the boycott had substantial anticompetitive effects; the boycott had no counterbalancing pro-competitive effects; and the AMA's unlawful conduct injured the plaintiffs.

Despite the fact that the district court found the conspiracy ended in 1980, it concluded that the illegal boycott's "lingering effects" still threatened plaintiffs with current injury and ordered injunctive relief. The court concluded that the boycott caused injury to chiropractors' reputations which had not been repaired, and current economic injury to chiropractors. Further, the AMA never affirmatively acknowledged that there are no impediments to professional association and cooperation between chiropractors and medical physicians, except as provided by

law. Thus, chiropractors continued to suffer because the boycott's negative effects (namely, inhibiting AMA members' individual decision-making in their relationships with chiropractors) still remained. The district court believed it was important that the AMA make its members aware of the present AMA position (i.e., it is ethical for medical physicians to professionally associate with chiropractors, if the physician believes it is in the patient's best interest) to eliminate the illegal boycott's lingering effects, and ordered an injunction designed to accomplish that result. 671 F. Supp. at 1507-08 (form of injunction).

II.

A. *Noerr-Pennington Doctrine*

[1] The AMA complains that the district court relied almost entirely on AMA conduct that was protected under the Noerr-Pennington doctrine in finding that it illegally conspired to restrain trade. *Eastern Railroad Presidents' Conference v. Noerr Motor Freight Inc.*, 365 U.S. 127, 5 L. Ed. 2d 464, 81 S. Ct. 523 (1961); *United Mineworkers v. Pennington*, 381 U.S. 657, 14 L. Ed. 2d 626, 85 S. Ct. 1585 (1965). *See also California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 30 L. Ed. 2d 642, 92 S. Ct. 609 (1972). The Noerr-Pennington doctrine protects businesses and other associations when they join to petition legislative bodies, administrative agencies, or courts for actions having anticompetitive consequences. *Id. See also Wilk I*, 719 F.2d at 229. The doctrine does not, however, protect purely private action, not genuinely aimed at prompting governmental action. *See Allied Tube and Conduit Corp. v. Indian head, Inc.*, 486 U.S. 492, 108 S. Ct. 1931, 100 L. Ed. 2d 497 (1988).

[2] The AMA contends that its statements regarding chiropractors were either statements about chiropractic's deficiencies or bona fide opinions on matters of public

interest. The district court acknowledged the AMA's claim and, to the extent that the Committee's work regarding influencing legislation on the state and federal levels or in informational activities to inform the public on the nature of chiropractic was involved, it did not consider such conduct in reaching its decision. *Wilk*, 671 F. Supp. at 1473 n. 2. But apart from the protected activity, the district court found substantial evidence of acts aimed at achieving the boycott's goals, not legislative action. *Id.* at 1473-77.

The court found that the AMA, through a resolution recommended by its Board of Trustees, and adopted by its House of Delegates, branded chiropractic "an unscientific cult." 671 F. Supp. at 1473. This implicitly invoked Principle 3's ethical proscription on professional association with chiropractors. Subsequent AMA action, *id.* at 1473-74, made clear the ethical bar on professional association (which included prohibiting medical physicians from referring patients to chiropractors, and from receiving referrals from chiropractors; providing diagnostic, laboratory, or radiology services for chiropractors; and from teaching chiropractors, or practicing together in any manner). The AMA widely circulated these documents. The court also found the Committee had regularly communicated with medical boards and associations, informing them that professional association between medical physicians and chiropractors was unethical. 671 F. Supp. at 1473.

We disagree with the AMA that the district court "repeatedly [cited]" AMA documents which "[focused] entirely on the AMA's 'vigorous educational program' and on 'the necessity to move aggressively against chiropractic in the state legislatures." One such document the AMA points to is an internal AMA memorandum (PX 464, Jt.App. 776-77) from the Committee to the Board of Trustees, discussing the AMA's goal of "the containment of chiropractic and, ultimately, the elimination of chiropractic."

It expressly disavows any intention of using the document publicly. And while the document details some activity that was likely protected, it suggests that activity may have been done only "to minimize the chiropractic argument that the [AMA's] campaign is simply one of economics. . . ." (Jt.App. 777). Also falling outside of the Noerr-Pennington doctrine's protection is an AMA Judicial Council opinion, holding that it was unethical for medical physicians to professionally associate with chiropractors, which was circulated to AMA members and to 56 medical specialty boards (Jt.App. 801-03). Finally, in 1973, the AMA drafted "Standard X," which incorporated the unscientific practitioners' ethical bar into the JCAH accrediting standards. At the AMA's urging, JCAH adopted Standard X.

These activities were not aimed at obtaining legislative action. They were instead aimed at medical physicians and hospitals, cautioning them that it was unethical and indeed dangerous (the obvious inference from receiving health care from an unscientific cult) to associate professionally with chiropractors. In the face of the district court's specific findings on this issue, we cannot say it erred in relying on these activities.

B. *Unreasonable Restraint of Trade*

[3][4] The central question in this case is whether the AMA's boycott constituted an unreasonable restraint of trade under § 1 of the Sherman Act. A restraint is unreasonable if it falls within the category of restraints held to be per se unreasonable, or if it violates what is known as the "Rule of Reason." *Federal Trade Commission v. Indiana Federation of Dentists*, 476 U.S. 447, 457-58, 90 L. Ed. 2d 445, 106 S. Ct. 2009 (1986); *NCAA v. Board of Regents of the University of Oklahoma*, 468 U.S. 85, 103, 82 L. Ed. 2d 70, 104 S. Ct. 2948 (1984); *National Society of Professional Engineers v. United States*, 435 U.S. 679, 692, 55 L. Ed. 2d 637, 98 S. Ct.

1355 (1978). Restraints that are per se unreasonable include agreements whose nature and necessary effect are so plainly anticompetitive that no elaborate study of the industry or restraint is needed to establish their illegality. *Nat'l. Society of Professional Engineers*, 435 U.S. at 692. Concerted refusals to deal, described as group boycotts, typically are held unlawful *per se*. *See Indiana Federation of Dentists*, 476 U.S. at 458; *Consolidated Metal Products, Inc. v. American Petroleum Institute*, 846 F.2d 284, 290 (5th Cir. 1988). The per se rule avoids a burdensome inquiry into actual market conditions where the likelihood of anticompetitive effect is so obvious that the costs of determining whether the particular restraint at issue involves anticompetitive conduct is unwarranted. *Jefferson Parish Hospital District No. 2 v. Hyde*, 466 U.S. 2, 15-16 n. 25, 80 L. Ed. 2d 2, 104 S. Ct. 1551 (1984). In contrast, the rule of reason category includes agreements whose competitive effect can only be evaluated by analyzing the facts peculiar to the business involved, the particular restraint's history, and the reasons it was imposed. *Nat'l. Society of Professional Engineers*, 435 U.S. at 692. The test of legality under the rule of reason is whether the challenged conduct promotes or suppresses competition. *Id.* at 691; *see also Chicago Board of Trade v. United States*, 246 U.S. 231, 238, 62 L. Ed. 683, 38 S. Ct. 242 (1918). The purpose of both approaches (*per se* or rule of reason) is to decide the restraint's competitive significance.

The Supreme Court historically has been slow to condemn rules adopted by professional associations as unreasonable *per se*. *Indiana Federation of Dentists*, 476 U.S. at 458. The Court is also reluctant to extend the *per se* rule to restraints imposed in the context of business relationships where a practice's economic impact is not immediately apparent. *Id.* Likewise, judicial inexperience with a particular arrangement cautions against extending the *per se* approach's reach insofar as judging the alleged restraint's lawfulness under the antitrust laws. *NCAA v. Board of*

Regents, 468 U.S. at 100 n.21; *see also Northwest Wholesale Stationers, Inc. v. Pacific Stationery and Printing Co.*, 472 U.S. 284, 294, 86 L. Ed. 2d 202, 105 S. Ct. 2613 (1985); *Arizona v. Maricopa County Medical Society*, 457 U.S. 332, 344, 73 L. Ed. 2d 48, 102 S. Ct. 2466 (1982); *Consolidated Metal Products*, 846 F.2d at 290. Nevertheless, the Supreme Court has not refrained from applying the *per se* approach solely on the grounds that the judiciary has little antitrust experience in the particular industry. *See Arizona v. Maricopa County Medical Society*, 457 U.S. at 349-51 (health care industry).

[5] As a general rule, § 1 claims under the Sherman Act should be evaluated under the rule of reason unless the challenged action falls into the category of agreements which are deemed so harmful in their effect on competition so as to be conclusively presumed to be unreasonable and thus illegal without a detailed inquiry as to the precise harm they are alleged to have caused. *Northwest Wholesale Stationers*, 472 U.S. at 289-90; *Consolidated Metal Products*, 846 F.2d at 289-90. In this court's first go-round with this case, it held that the AMA's alleged boycott should be measured under the rule of reason. *Wilk I*, 719 F.2d at 221-22. We held that in the context of a learned profession, the nature and extent of the restraint's anticompetitive effect was too uncertain to warrant *per se* treatment. *Id.* at 221. Moreover, we looked to the Supreme Court's decisions involving professional associations (*e.g., Arizona v. Maricopa County Medical Society*, 457 U.S. 332, 73 L. Ed. 2d 48, 102 S. Ct. 2466 ; *Nat'l. Society of Professional Engineers*, 435 U.S. 679, 55 L. Ed. 2d 637, 98 S. Ct. 1355 ; and *Goldfarb v. Virginia State Bar*, 421 U.S. 773, 44 L. Ed. 2d 572, 95 S. Ct. 2004 (1975)), and noted the pains the Court had taken to carve out the possibility that a practice which might violate the Sherman Act in another context might not violate the Act when a learned profession was involved. *Wilk I*, 719 F.2d at 222. Thus, we concluded, "[a] canon of medical ethics purporting, surely not frivolously, to address the importance of scientific

method gives rise to questions of sufficient delicacy and novelty at least to escape *per se* treatment." *Id.*

On appeal, plaintiffs urge that we change course and apply instead the *per se* rule. Plaintiffs claim that the Supreme Court's decisic in *Indiana Federation of Dentists and Northwest Wholesa.. Stationers* undercut our prior decision to treat this case under the rule of reason. But like the district court, we decline plaintiffs' invitation to revisit this issue. The Court in *Indiana Federation of Dentists* did not itself apply a *per se* rule. Nor do we read either case as requiring us to employ the *per se* analysis on the facts of this case. And, in any event, even under the rule of reason, the boycott was unlawful. *Cf. Parts and Electric Motors, Inc. v. Sterling Electric, Inc.*, 826 F.2d 712, 720-21 (7th Cir. 1987) (because jury had concluded that the challenged action -- an alleged tying arrangement -- had unreasonably restrained competition, and had found liability under the rule of reason, it was unnecessary to decide the case under the *per se* inquiry).

[6][7] The threshold issue in any rule of reason case is market power. *Schachar v. American Academy of Ophthalmology, Inc.*, 870 F.2d 397, 398 (7th Cir. 1989); *Valley Liquors, Inc. v. Renfield Importers Ltd.*, 822 F.2d 656, 666 (7th Cir. 1987) (*Valley II*). Market power is the ability to raise prices above the competitive level by restricting output. *NCAA v. Board of Regents*, 468 U.S. at 109 n. 38; *Ball Memorial Hospital*, 784 F.2d at 1331. Whether market power exists in an appropriately defined market is a fact-bound question, and appellate courts normally defer to district court findings on that issue. *Jefferson Parish Hospital*, 466 U.S. at 42 (O'Connor, J., concurring). Here, the district court found the relevant market to be the provision of health care services to the American public nationwide, particularly care for the treatment of musculoskeletal problems. 671 F. Supp. at 1478. Several facts demonstrated the AMA's market power within

the health care services market. AMA members constituted a substantial force in the provision of health care services in the United States and they constituted a majority of medical physicians. AMA members received a much greater portion of fees paid to medical physicians in the United States than non-AMA members. *Id.* The evidence showed that AMA members received approximately 50% of all fees paid to health care providers. Finally, according to plaintiffs' expert, the AMA enjoyed substantial market power. The district court also found there was substantial evidence that the boycott adversely affected competition, and that a showing of such adverse effects negated the need to prove in any elaborate fashion market definition and market power, relying on *Indiana Federation of Dentists*, 476 U.S. at 460-62, 106 S. Ct. at 2018-20.

The AMA first contests the district court's finding of market power. It challenges the court's reliance on market share evidence as a basis to find market power and the district court's lumping together all AMA members as a group in assessing market share as a basis for its market power finding. We are not convinced the trial court erred. The district court properly relied on the AMA membership's substantial market share in finding market power. While we cautioned against relying solely on market share as a basis for inferring market power in *Ball Memorial Hospital*, 784 F.2d at 1336, we did not rule out that approach. *Id. See also Parts and Electric Motors*, 826 F.2d at 720 n. 7; *Valley II*, 822 F.2d at 666-67. This is especially so where there are barriers to entry and no substitutes from the consumer's perspective. *Ball Memorial Hospital*, 784 F.2d at 1336. Here the district court found the AMA membership was a substantial force in the American health care market, and that there were substantial barriers to the entry of new chiropractors into the field, such as substantial education requirements, 671 F. Supp. at 1479.

The district court also relied on substantial evidence of adverse effects on competition caused by the boycott to establish the AMA's market power. In *Indiana Federation of Dentists,* the Supreme Court explained that since "the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, 'proof of actual detrimental effects, such as reduction of output' can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effects.'" 476 U.S. at 460-61, 106 S. Ct. at 2018-19, quoting 7 P. Areeda, *Antitrust Law* ¶. 1511, p. 429 (1986). *See also,* P. Areeda, *The Rule of Reason -- A Catechism on Competition,* 55 Antitrust Law Journal 571, 577 (1986). Thus, the district court recited the boycott's anticompetitive effects:

> It is anticompetitive and it raises costs to interfere with the consumer's free choice to take the product of his liking; it is anticompetitive to prevent medical physicians from referring patients to a chiropractor; (Lynk -- 1427-28) it is anticompetitive to impose higher costs on chiropractors by forcing them to pay for their own x-ray equipment rather than obtaining x-rays from hospital radiology departments or radiologists in private practice; and it is anticompetitive to prevent chiropractors from improving their education in a professional setting by preventing medical physicians from teaching or lecturing to chiropractors. (Tr. 1409-22, 1424-31.)

671 F. Supp. at 1478-79. See also Wilk I, 719 F.2d at 214. These findings eliminated the need for an inquiry into market power.

[8] The AMA's attempts to discredit the evidence the district court relied on to find anticompetitive effects are unavailing. The record does not show, as the AMA

contends, that forcing chiropractors to purchase their own x-ray equipment had no adverse effect on chiropractors. And the district court did not clearly err in finding that former Principle 3 reduced demand for chiropractic services simply because there was evidence that a patient had seen a chiropractor before and after having seen a medical physician. Moving on, the AMA argues that even if market power existed, it escapes liability under the rule of reason because former Principle 3 had overriding pro-competitive effects. The AMA's argument is not unpersuasive in the abstract; but unfortunately it relies on evidence which the district court rejected as "speculative." 671 F. Supp. at 1479. Essentially, the AMA argues that the market for medical services is one where there is "information asymmetry." In other words, health care consumers almost invariably lack sufficient information needed to evaluate the quality of medical services. This increases the risk of fraud and deception on consumers by unscrupulous health care providers possibly causing what the AMA terms "market failure": consumers avoiding necessary treatment (for fear of fraud), and accepting treatment with no expectation of assured quality. The AMA's conduct, the theory goes, ensured that physicians acquired reputations for quality (in part, by not associating with unscientific cultists), and thus allowed consumers to be assured that physicians would use only scientifically valid treatments. This in effect simultaneously provided consumers with essential information and protected competition.

Getting needed information to the market is a fine goal, but the district court found that the AMA was not motivated solely by such altruistic concerns. Indeed, the court found that the AMA intended to "destroy a competitor," namely, chiropractors. It is not enough to carry the day to argue that competition should be eliminated in the name of public safety. *See Nat'l. Society of Professional Engineers*, 435 U.S. 679, 55 L. Ed. 2d 637, 98 S. Ct. 1355.

But the AMA persists in arguing that pro-competitive effects were achieved by the boycott through what its expert called "nonverbal communication." In rejecting this argument, the district court stated that the AMA's expert's

> theory is that the boycott constituted nonverbal communication which informed consumers about the differences between medical physicians and chiropractors, and that this had a pro-competitive effect. (Tr. 1411-12.) I reject this opinion as speculative. (Tr. 1434-43.) Mr. Lynk [William J. Lynk, the AMA's expert] neither conducted nor read any studies regarding the efficacy of such nonverbal communications. *Id.* He neither conducted nor read any surveys of consumer opinion to determine whether consumers were confused about the differences between medical physicians and chiropractors. (*Id.*) I saw no evidence of any such confusion during the trial. Mr. Lynk's opinion does not accord with common sense. A nationwide conspiracy intended by its participants to contain and eliminate a licensed profession cannot be justified on the basis of Mr. Lynk's personal opinion that it was pro-competitive, nonverbal communication to consumers.

671 F. Supp. at 1479. We find the district court's reasoning compelling.

The AMA, however, argues that the district court missed the boat in rejecting Mr. Lynk's theory. The relevant question, according to the AMA, is not whether consumers would perceive any differences between physicians and chiropractors today; rather, it is whether they would ever view a physician's *referral* of a patient to a chiropractor as a physician's endorsement of the chiropractor's practices. But

the AMA misses the essence of the district court's ruling. The trial court rejected the AMA's theory as speculative because Lynk neither conducted nor read any studies regarding nonverbal communications; his views were only his "personal opinion." 671 F. Supp. at 1479. In fact, Lynk testified that an empirical study could not even be performed to determine the pro-competitive effects of Principle 3. (Jt.App. at 351-52.) Thus, even if the AMA is right in asserting that the relevant inquiry is how a physician's referral would be viewed by the consumer, there was no underlying study or data to support its theory.

Moreover, Lynk's testimony did not bear out the AMA's assertions regarding the "relevant question." The AMA says that it is irrelevant to its theory whether health care consumers perceive any differences between chiropractors and medical physicians, and that Lynk's testimony went to the role of reputation and information in health care service markets. But in testifying as to the pro-competitive function of standards generally, Lynk testified that they improve consumer information by making it possible for consumers to make more informed choices "about what it is they are getting from alternative sellers of the same or substitute products to the extent that it allows them to make better choices." (Jt.App. 343.) Lynk also testified that one of the interests served by former Principle 3 was that it would clarify the distinctions between the profession of medicine and alternative professions "that are not based on medical science but which can create the appearance that they are." (Jt.App. 351.) This seems to go precisely to the perceived differences between chiropractors and medical physicians.

In sum, we agree with the district court that the AMA's boycott constituted an unreasonable restraint of trade under § 1 of the Sherman Act under the rule of reason. Therefore, the district court's findings that the AMA's boycott was anticompetitive, and was not counter-balanced by any pro-

competitive effects were not erroneous. *Nat'l. Society of Professional Engineers*, 435 U.S. at 691.

C. *Patient Care Defense*

In the AMA's first appeal, we modified the rule of reason to allow the AMA to justify its boycott of chiropractors if it could show that it was motivated by a concern for "patient care." *Wilk I*, 719 F.2d at 227. We were persuaded that measuring former Principle 3's reasonableness required a more flexible approach than the traditional rule of reason inquiry provided. *Id.* at 226-27. Thus, we explained that if plaintiffs met their burden of persuasion on remand by showing that former Principle 3 and the implementing conduct had restricted competition rather than promoting it, the burden of persuasion would shift to the defendants to show:

> (1) that they genuinely entertained a concern for what they perceive as scientific method in the care of each person with whom they have entered into a doctor-patient relationship; (2) that this concern is objectively reasonable; (3) that this concern has been the dominant motivating factor in defendants' promulgation of Principle 3 and in the conduct intended to implement it; and (4) that this concern for scientific method in patient care could not have been adequately satisfied in a manner less restrictive of competition.
>
> *Id.* at 227.

In this appeal, plaintiffs ask us to reconsider the patient care defense, urging that three subsequent Supreme Court decisions have implicitly rejected it; *see Patrick v. Burget*, 486 U.S. 94, 104-05, 100 L. Ed. 2d 83, 108 S. Ct. 1658 (1988); *Indiana Federation of Dentists*, 476 U.S. at 458-60; and *Jefferson*

Parish Hospital Dist. No. 2, 466 U.S. at 25 n. 41. While these decisions may cast doubt on the patient care defense's continuing vitality, they did not address the specific issue of whether the patient care defense on the facts in this case would be allowed. While we acknowledge that there has been some academic criticism of the defense (*see Kissam Antitrust Boycott Doctrine*, 69 Iowa L. Rev. 1165, 1214-16 (1984); Havighurst, *Doctors and Hospitals; An Antitrust Perspective on Traditional Relationships*, 1984 Duke L.J. 1071, 1103 n. 101 (1984)), we need not revisit the issue because the district court's finding that the AMA did not satisfy its burden of persuasion under the defense was not clearly erroneous.

The district court held that the AMA failed to meet the defense's second and fourth elements: that its concern for scientific method in patient care was objectively reasonable, and that the concern for scientific method in patient care could not have been satisfied adequately in a manner less restrictive of competition, respectively. While only those two rulings are at issue, it is useful to summarize the district court's treatment of the entire defense.

Although doubting the AMA's genuineness regarding its concern for scientific method in patient care, the district court concluded that the AMA established that element. While it was attacking chiropractic as unscientific, the AMA simultaneously was attacking other unscientific methods of disease treatment (e.g., the Krebiozen treatment of cancer), and, as the district court noted, the existence of medical standards or guidelines against unscientific practice was relatively common. 671 F. Supp. at 1481. The court, however, found that the AMA failed to carry its burden of persuasion as to whether its concern for scientific method in patient care was objectively reasonable.

The court acknowledged that during the period that the Committee on Quackery was operating, there was plenty of material supporting the belief that all chiropractic was unscientific. But, according to the court (and this is unchallenged), at the same time, there was evidence before the Committee that chiropractic was effective, indeed more effective than the medical profession, in treating certain kinds of problems, such as back injuries. The Committee was also aware, the court found, that some medical physicians believed chiropractic could be effective and that chiropractors were better trained to deal with musculoskeletal problems than most medical physicians. Moreover, the AMA's own evidence suggested that at some point during its lengthy boycott, there was no longer an objectively reasonable concern that would support a boycott of the entire chiropractic profession. Also important was the fact that "it was very clear" that the Committee's members did not have open minds to pro-chiropractic arguments or evidence. 671 F. Supp. at 1481-83.

Next, the court found that the AMA met its burden in establishing that its concern about scientific method was the dominant motivating factor for promulgating former Principle 3, and in the conduct undertaken and intended to implement it. 671 F. Supp. at 1483. But even so, the court acknowledged there was evidence showing that the AMA was motivated by economic concerns, as well

Finally, the court concluded that the AMA failed to meet its burden in demonstrating that its concern for scientific method in patient care could not have been satisfied adequately in a manner less restrictive of competition. The court stated that the AMA had presented no evidence of other methods of achieving their objectives such as public education or any other less restrictive approach. 671 F. Supp. at 1483.

[9] The AMA attacks the district court's findings as to the second element (concern for scientific method as objectively reasonable), claiming that the court rewrote the element to require the AMA to show its concern with chiropractic (rather than with scientific patient care) was objectively reasonable. *Wilk*, 671 F. Supp. at 1481. We disagree. The AMA's claim in passing that the court "[misconceived]" the defense is barely explained in one of its 67 footnotes; but in any event, we think the district court was true to the defense and adequately supported its holding with several key factual determinations. It recited the evidence directly at odds with the AMA's belief that all chiropractic was unscientific. 671 F. Supp. at 1481-83. The AMA does not challenge the district court's findings, so those findings must stand. Beyond that, the AMA reads this element too rigidly. The issue here is whether its concern for scientific method in the care of patients was objectively reasonable. In the context of this particular case, then, the question is whether that concern justified a boycott of chiropractic. Based on the undisputed facts, it did not.

The AMA's challenge to the fourth element (concern for scientific method in patient care could not have been adequately satisfied in a manner less restrictive of competition) is equally unpersuasive. The AMA completely fails to offer any evidence to support its burden. Instead, it argues that its former guideline had at most a de minimis effect on chiropractors' costs, and thus could not be treated as an attempt to contain and eliminate the entire chiropractic profession. This, however, ignores the fact that the AMA's self-proclaimed and described "mission" was to contain, and ultimately eliminate chiropractic. (Jt. App. 776.) The AMA participated in a nationwide boycott and conspiracy designed to contain and eliminate a profession that was licensed in all fifty states at the time the Committee on Quackery was disbanded. As the district court held, it is "a difficult task" to argue that this was "the only way to

satisfy the AMA's concern for the use of scientific method in patient care." 671 F. Supp. at 1483. Furthermore, we reject the AMA's attempts to minimize the effect its boycott had on competition. The district court found the boycott had several anticompetitive effects, such as raising costs by interfering with consumers' free choice, which are unrefuted. 671 F. Supp. at 1478-79, 1480. [FN2]

FN2. The AMA;s assertion that former Principle 3 operated to prevent the "free-riding" that would have occurred if physicians had referred patients to chiropractors misses the mark. Apparently, the AMA believes that if physicians were forced to refer patients to chiropractors, chiropractors would benefit (the "free ride") from the physicians' reputation for providing quality medical service, without necessarily deserving that reputation themselves. But neither this court nor the district court would require the AMA to endorse chiropractic, nor do we mandate that there be referrals. We simply speak to the restraint on professional association, and say that physicians, hospitals, and other institutions must be free to make their own uncoerced decisions on whether to professionally associate with chiropractors. We do not compel medical physicians to praise or sponsor chiropractors' work. *See Schachar v. American Academy of Ophthalmology*, 870 F.2d 397, 399 (7th Cir. 1989). We do not even require "cooperation or friendliness." *Id.* We also note that the AMA apparently misconceives the role of the free-riding analysis in antitrust law. *See Premier Electrical Construction Co. v. National Electrical Contractors Ass'n Inc.*, 814 F.2d 358, 368-70 (7th Cir. 1987) (explaining the concept).

D. *Antitrust Injury*

[10] To seek an injunction under § 16 of the Clayton Act, a private plaintiff must allege "threatened loss or damage 'of the type the antitrust laws were designed to prevent and that flows from that which makes defendants' acts unlawful.'" *Cargill Inc. v. Monfort of Colorado Inc.*, 479 U.S. 104, 113, 93 L. Ed. 2d 427, 107 S. Ct. 484 (1986) (*quoting Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489, 50 L. Ed. 2d 701, 97 S. Ct. 690 (1977)). Here, the district court concluded that plaintiffs had shown the kind of injury the antitrust laws were designed to prevent. 671 F. Supp. at 1479-80. Plaintiff's economic expert (Stano) compared chiropractors' incomes with podiatrists' and optometrists' incomes (comparable limited license practitioners) over the relevant period of time and concluded that chiropractors' incomes had been lower than both. This Styno viewed as consistent with plaintiffs' boycott theory. He also concluded that a jump in chiropractors' incomes during the 1978-1980 period was consistent with the acknowledged lessening of the boycott by the AMA during that time. Lynk, the AMA's economic expert, though he faulted the data plaintiffs' expert relied upon, agreed that if he were to compare chiropractors' incomes to comparable groups, he also would include podiatrists and optometrists (although he stated he would seek further explanations for differences between the groups' incomes). In the district court's view, further support for plaintiffs' theory of harm was the "very strong evidence of a pervasive, nationwide, effective conspiracy which by its very nature would have affected the demand curve for chiropractic services and adversely affected the income of chiropractors." 671 F. Supp. at 1480. Finally, the district court added, there was evidence of injury to reputation suffered by chiropractors. (Both economic experts, according to the court, believed that injury to reputation would constitute an anticompetitive effect of the boycott.)

The AMA argues that plaintiffs failed to establish an antitrust injury. Essentially the argument goes somewhat like this. This case is not a class action; rather, it involves only the four named plaintiffs. The only harm here would have been to "scientific" chiropractors. Because, according to the AMA (but not the district court), plaintiffs were not and are not "scientific practitioners," they could not have suffered any injury from former Principle 3. If any chiropractors could establish antitrust injury, it would be those who have "renounced the theory of sublaxations and limit their practices to conservative physical therapy modalities." The AMA's argument thus hinges on its lengthy assertion that the four plaintiffs are "unscientific practitioners." The problem with this approach, however, is that the district court did not agree with the AMA that the plaintiffs were "unscientific" practitioners. Although the court acknowledged that there was some evidence that the plaintiffs did not use common methods in treating common symptoms, and that the treatment of patients appeared to be undertaken on an ad hoc rather than on a scientific basis, it did not go so far as the AMA believes, and establish or find that the plaintiffs in this case were "unscientific practitioners." Indeed, it expressly held that no one involved in the case, including the plaintiffs, believed that chiropractic treatment should be used for treatment of diseases such as cancer, diabetes, heart disease, high blood pressure, and infections. 671 F. Supp. at 1482. Regardless, neither the district court, nor this court is equipped to determine whether chiropractic is "scientific" or not. So the AMA's argument must fail in any event. We see the AMA's argument here as yet another invitation to tackle the question of whether chiropractic is "either good or bad, efficacious or deleterious, quackery or science." 671 F. Supp. at 1481. The district court repeatedly stated it was not deciding whether chiropractic was scientific. 671 F. Supp. 1482 n. 8, 1482-83, 1506-07. Yet both sides (below it was

plaintiffs, 671 F. Supp. at 1482; here, it is the AMA) continue to color their arguments with how they view their own, or the other side's, profession. Like the district court, we do not see our task as deciding whether or not chiropractic is scientific.

The AMA also quibbles with the evidence of antitrust injury. The district court rejected the same arguments. 671 F. Supp. at 1480. We too are unpersuaded. The AMA offers no good reason why we should accept its expert's opinion over that of the plaintiffs', and we decline to do so. But beyond that, the district court relied on more than just plaintiffs' expert in determining there was an antitrust injury. It also relied on the evidence of the "pervasive, nationwide, effective conspiracy which by its very nature would have affected the demand curve for chiropractic services and therefore adversely affected income of chiropractors." 671 F. Supp. at 1480. (Further, we also note that the AMA is far too generous in its characterization of plaintiffs' expert's "concession" that the AMA's conduct was "lawful and pro-competitive.")

The evidence established that all chiropractors' incomes were lower than those of comparable limited license practitioners. And the evidence was that all chiropractors suffered an injury to their reputation. 671 F. Supp. at 1480. Indeed, the district court found that the individual plaintiffs suffered rejections and lost opportunities and that "the individual plaintiffs have been personally harmed, and continue to be personally threatened, by a lack of association with members of the AMA caused by the boycott and the lingering effects of the boycott." 671 F. Supp. at 1486. Moreover, the court stated that "[the] activities of the AMA undoubtedly have injured the reputation of chiropractors generally. This kind of injury more likely than not was sustained by the four plaintiffs." Id. This directly refutes the

AMA's contention that there was nothing but a showing of "classwide injury." [FN3]

FN3. The AMA cites *United States v. Borden Co.*, 347 U.S. 514, 74 S. Ct. 703, 98 L. Ed. 903 (1954), for the proposition that a showing of classwide injury is insufficient to support injunctive relief for an individual plaintiff. While that might be true, *Borden* does not say so. There, the Supreme Court held that in light of the differences in the interests sought to be vindicated by the government and by private litigants in actions under the Clayton Act, the government was not precluded from obtaining injunctive relief against price discrimination simply because, in an earlier private action, a decree enjoined the conduct in question. At any rate, the trial court here relied on more than evidence of "classwide injury" in finding that these four plaintiffs were injured by the AMA's unlawful boycott.

III.

Entitlement To Injunctive Relief

Section 16 of the Clayton Act provides that:

Any person, firm, corporation, or association shall be entitled to sue for and have injunctive relief . . . against threatened loss or damage by a violation of the antitrust laws . . . when and under the same conditions and principles as injunctive relief against threatened conduct that will cause loss or damage is granted by courts of equity, under the rules governing such proceedings. . . .

15 U.S.C. § 26. Although the district court concluded that the AMA's boycott ended in 1980 (when former Principle 3 was eliminated), it held that an injunction nevertheless was necessary in this case.

The trial court concluded there were lingering effects of the AMA's conspiracy; that the AMA never acknowledged the lawlessness of its past conduct, and in fact continued to maintain that it had always been in compliance with the antitrust laws; that the AMA had never affirmatively stated that it was ethical for medical physicians to professionally associate with chiropractors; that the AMA had never publicly stated to its members the admissions made in the trial court about chiropractic's improved nature, despite the fact that the AMA currently claims that it made changes in its policy in recognition of chiropractic's change and improvement; that the AMA never publicly retracted articles such as "The Right and Duty of Hospitals to Deny Chiropractor Access to Hospitals"; that a medical physician had to read very carefully the current AMA Judicial Council opinions to realize that there had been a change in the treatment of chiropractors; and, finally, that the AMA's systematic, long-term wrongdoing and long-term intent to destroy chiropractic "[suggested]" that an injunction was appropriate. 671 F. Supp. at 1488. The court believed that it was important to make AMA members aware of the AMA's present position -- that it is ethical for medical physicians to professionally associate with chiropractors, if the physician believes it is in his patient's best interest -- to eliminate the unlawful boycott's lingering effects. The injunction, then, is to "assure that the AMA does not interfere with the right of a physician, hospital or other institution to make an individual decision on the question of professional association." 671 F. Supp. at 1507.

The injunction requires the AMA to arrange publication of the district court's order in the *Journal of the American Medical Association*, mail the order to each of the AMA's members, and revise the current opinions of the AMA's Council on Judicial and Ethical Affairs (formerly the Judicial Council) so that it states the AMA's present position on chiropractic in a separate provision, with a heading and index references referring to chiropractors. 671 F. Supp. at 1507-08.

[11] The AMA correctly points out that the district court wrongly placed the burden of proof on the AMA in deciding whether injunctive relief was appropriate in this case. But the AMA does not argue how, if at all, the court's error prejudiced it. We do not think the AMA was prejudiced.

The district court treated the AMA's argument in this respect as an argument that the claim for injunction was moot instead of an argument that no injunctive relief was necessary. Although these concepts are similar, they are analytically distinct, and a court could find that a case is not moot yet deny injunctive relief. *See United States v. Concentrated Phosphate Export Association, Inc.*, 393 U.S. 199, 203, 89 S. Ct. 361, 21 L. Ed. 2d 344 (1968); *U.S. v. W.T. Grant*, 345 U.S. 629, at 633, 73 S. Ct. 894, at 898, 97 L. Ed. 1303 (1953); *TRW, Inc. v. Federal Trade Commission*, 647 F.2d 942, 953-54 (9th Cir. 1981); *SCM Corporation v. Federal Trade Commission*, 565 F.2d 807, 812 (2d Cir. 1977). There are practical differences between the concepts, as well. The mootness burden is a heavy one, and the *defendant* must show that there is no reasonable expectation that the wrong will be repeated. By contrast, the burden for showing whether injunctive relief is necessary is on the *moving party;* here plaintiffs. The district court wrongly placed the burden of persuasion on the AMA. 671 F. Supp. at 1484. But no matter which party bore the burden on this issue, the district

court's ultimate findings leave no doubt that injunctive relief was appropriate.

A party moving for an injunction must show some cognizable danger of recurrent violation, that is, something more than the mere possibility which serves to keep the case alive. *W.T. Grant*, 345 U.S. at 633, 73 S. Ct. at 898. "To be considered are the bona fides of the expressed intent to comply, the effectiveness of the discontinuance and, in some cases, the character of the past violations." *Id.* Courts require "clear proof" that an unlawful practice has been abandoned, and must guard against attempts to avoid injunctive relief "by protestations of repentance and reform, especially when abandonment seems timed to anticipate suit, and there is a probability of resumption." *U.S. v. Oregon State Medical Society*, 343 U.S. 326 at 333, 72 S. Ct. 690, at 695, 96 L. Ed. 978 (1952). These issues are committed to the trial court's discretion. *Id.* 345 U.S. at 634, 73 S. Ct. 898; *see also U.S. v. Concentrated Phosphate*, 393 U.S. at 203-04, 89 S. Ct. at 364. Thus, we will not substitute our judgment for the district court's. The question is not how we would rule if we were addressing the question in the first instance. Rather, the question is whether the district court's decision was reasonable. *See United States v. United States Currency in the Amount of $103,387.27*, 863 F.2d 555, 561 (7th Cir. 1988).

[12] We believe the court's decision was reasonable. It found a cognizable danger of recurrent violations, was unimpressed with the AMA's expressed intent to comply with antitrust laws, was unpersuaded by the effectiveness of the AMA's discontinuance of its boycott, and properly considered the systematic and long-term nature of the boycott. *W.T. Grant*, 345 U.S. at 633, 73 S. Ct. at 897.

The AMA characterizes many of its challenges to the district court's decision to order an injunction as attacks on the court's findings of fact. Thus, for example, the AMA argues that the district court "erroneously found a risk of recurrence." But the facts are relatively undisputed. The AMA is really challenging the district court's decision that those facts supported an injunction.

In this regard, the district court found that the AMA's behavior in connection with the 1983 revision of the JCAH accreditation standards for hospitals indicated the AMA's likelihood of returning to its old (anti-chiropractic) ways. (The facts surrounding the 1983 revisions are set out more fully in section IV below, in connection with plaintiffs' cross appeal against JCAH.) The AMA's original position toward those standards was favorable to chiropractors in that it supported the JCAH position that each hospital be permitted to decide for itself, under applicable state law, which licensed health care providers would be allowed hospital privileges and membership on the medical staff. However, after an outcry from its membership the AMA was forced to change its original position to satisfy its constituents, namely, medical physicians; it thus sought to have JCAH approve a more restrictive accreditation standard which would ensure medical and osteopathic physicians control of the medical staff and patient care in hospitals. 671 F. Supp. at 1476, 1488. This incident led the trial court to conclude that the AMA's "present assurances [were] good only until the next chiropractic battle." *Id.* at 1488.

The facts surrounding the 1983 JCAH revisions are not in dispute. Even so, the AMA terms the district court's reliance on this incident as "baffling." Thus, it contends that even under the district court's injunction order it will still be allowed to urge restrictions on chiropractors before recognized accrediting bodies, and that its conduct

regarding the JCAH standards would be consistent with that mandate. The AMA also argues that the district court's conclusion that the JCAH's 1983 revision was reasonable, indeed proper, validates the AMA's call to action to ensure medical and osteopathic physician control of medical staff and patient care. We disagree.

While the AMA, under the district court's order, may in the future be free to urge restrictions or take positions with respect to chiropractic, the AMA's action with respect to the 1983 JCAH revisions must be viewed in the context in which it occurred. It came on the heels of a lengthy illegal boycott of chiropractors. And although the AMA believed the JCAH's initial standards were consistent with the then current antitrust legal climate, it was unable to maintain its position in the face of a barrage of criticism from its members. 671 F. Supp. at 1476-77. That coupled with the fact that the district court found the AMA even through the date of trial continued to respond to requests for information on chiropractic by sending out anti-chiropractic literature, *id.*, was enough for the district court properly to conclude that there was evidence that suggests a possible return to the AMA's former policies. Finally, the JCAH's action in 1983, although found reasonable and proper, is wholly distinct from the AMA's action. JCAH was an independent body, motivated by completely different concerns. Thus, while the AMA was attempting to contain and eliminate competitors (i.e., chiropractic), JCAH was acting only to assure that responsibility for patient care in acute care hospitals remained in the hands of medical and osteopathic physicians, the only practitioners who could perform that acute care.

In challenging the need for an injunction, the AMA also contends that it is legally bound by settlements in three separate chiropractic antitrust lawsuits to the position that chiropractors are licensed limited practitioners and that no

form of professional association with chiropractors is unethical. These settlements, according to the AMA, eliminate any threat that the boycott will recur. Again, we disagree. Although the settlements may be some evidence militating against the likelihood of recurrence, it is not so strong as to reverse the district court's determination. The trial court considered this evidence, 671 F. Supp. at 1487-88, but found it was outweighed by other evidence (recited above in connection with the JCAH 1983 revisions) of a risk of a return to the AMA's former policies. *Id.* at 1488. Notably, the district court found it relevant that in all of the settlements, there was no admission of liability.

The AMA additionally argues that the permanence of its post-1977 guidelines (and hence the unlikelihood of a return to its old ways) is emphasized by the "fact" that they were undertaken entirely independently of this lawsuit. However, the district court never found this "fact"; and the district court could properly be skeptical of the AMA's "protestations of repentance and reform," *Oregon State Medical Society*, 343 U.S. at 333, 72 S. CT. at 696, especially since the AMA's change of position occurred not too long after this suit was filed in 1976.

Another factor supporting the injunction is that the AMA still vigorously maintains that its boycott activity was lawful, and has never acknowledged its past conduct's lawlessness. This coupled with the AMA's begrudging statement on professional association with chiropractors was sufficient for the district court to doubt (1) the AMA's intent to comply with the antitrust laws in the future absent an injunction, and (2) the effectiveness of the discontinuation of its illegal conduct. Importantly, the district court found that even as of the trial date, the AMA continued to respond to requests for information on chiropractic by sending outdated anti-chiropractic literature. Further, none of the AMA's policies contain any affirmative

statement that the boycott is over. An example of the AMA's begrudging and ineffective removal of the ethical bar to professional association is Opinion 3.01 of its Judicial Council. The AMA cites Opinion 3.01 as evidence that its revised guideline has eliminated the prior guidelines on chiropractic, and removed any negative references to specific licensed limited practitioners. But as the district court noted, Opinion 3.01 is entitled "Nonscientific Practitioners." [FN4] Thus, the AMA member still must look under the heading "Nonscientific Practitioners" to discover that it is now permissible to associate with chiropractors. Any beneficial effect of Opinion 3.01 likely is lost because it is buried in a category almost certain to conjure up the ethical prohibitions of the past.

FN4. In 1980, the AMA adopted a new set of "Principles of Medical Ethics" that replaced the former "Principles" that had been in place since 1957. The 1980 "Principles" provide in part:

3.0 OPINIONS ON INTERPROFESSIONAL RELATIONS

3.01 NONSCIENTIFIC PRACTITIONERS. It is wrong to engage in or to aid and abet in treatment which has no scientific basis and is dangerous, is calculated to deceive the patient by giving him false hope, or which may cause the patient to delay in seeking proper care until his condition becomes irreversible.

Physicians should also be mindful of state laws which prohibit a physician from aiding and abetting an unlicensed person in the practice of medicine, aiding or abetting a person with a limited license in providing services beyond the scope of his license, or undertaking the joint medical treatment of patients under the foregoing circumstances.

A physician is otherwise free to accept or decline to serve anyone who seeks his services, regardless of who has recommended that the individual see the physician.

3.02 OPTOMENTRY. It is not unethical for an ophthalmologist to employ an optometrist as ancillary personnel to assist him provided the optometrist is identified to patients as an optometrist. A physician may send his patient to a qualified and ethical optometrist for optometric services. The physician would be ethically remiss, of course, if before doing so he did not insure that there was an absence of any medical reason for his patient's complaint, and he would be equally remiss if he sent a patient without having made a medical evaluation of the patient's condition. Physicians may teach in recognized schools of optometry for the purpose of improving the quality of optometric education. The scope of this teaching may embrace subjects within the legitimate scope of optometry which are designed to prepare students to engage in optometry within the limits prescribed by law.

(Jt.App. 1416.) Compare the treatment of optometrists and chiropractors. One has to look in the category of "nonscientific practitioners" to learn that it is ethical to associate with chiropractors. But there is a separate section devoted to optometrists, about whom the AMA at one time had some very negative things to say. 671 F. Supp. At 1487.

Yet another factor supporting an injunction is what the district court termed the boycott's lingering effects." The court found not only that plaintiffs had been personally harmed by the boycott, but that they continued to be

personally harmed and threatened by a lack of association with members of the AMA as a result of the boycott and its lingering effects. 671 F. Supp. at 1486. The boycott, while it was in full bloom, "more likely than not affected individual decision-making by AMA members and other medical physicians in their relationship with chiropractors;" and until AMA members learn that the AMA's policies in fact have changed, AMA members' decision-making with respect to professional association with chiropractors will continue to be affected, according to the trial court. The evidence amply supported this conclusion. It is based not only on the lengthy and successful boycott, but on the begrudging nature of the AMA's more recent and lawful changes.

The district court also found a continuing injury to chiropractors' reputation as a result of the boycott. Because the AMA has never made any attempt to publicly repair that damage, the court found that chiropractors will continue to suffer injury to reputation from the boycott. 671 F. Supp. at 1486-87. The AMA's publication of its changes and its settlements were not enough, in the eyes of the district court, to overcome these harmful effects. The AMA has not convinced us that the district court was wrong in this assessment.

The AMA's strongest challenge comes to the district court's findings with respect to the lingering effects on chiropractors' incomes. The court found that the injury to chiropractors' incomes threatened to continue through the date of trial. 671 F. Supp. at 1487. For this it relied on plaintiffs' expert's analysis regarding chiropractic income levels through 1986. (Jt.App. 57.) The court found this continuing harm existed, even though plaintiffs' expert's last data point showed that chiropractors' income in 1984 exceeded that of podiatrists and optometrists – the comparable professions. 671 F. Supp. at 1487. The court did

not, however, "find," as the AMA contends, that chiropractors' incomes had actually increased in 1984; rather, it only acknowledged the expert's data in this regard. *Id.* Obviously, given its finding regarding 1986 income levels (i.e., that chiropractors' incomes continued to suffer), the court was more persuaded by the expert's income projections into 1986 regarding the lagging of chiropractors' income, than by the 1984 data. The AMA's assertion that there is no basis for the district court to, rely on the projection of chiropractors' income is baseless. There was testimony that chiropractors' incomes would still have suffered in 1986 as a result of the boycott. (Jt.App. 57.) But even without the lingering effects on chiropractors' income, there still remain the effects on professional association and reputation, which by themselves may be sufficient to show continuing harm from the boycott.

In sum, even though the district court wrongly allocated the burden of proof in deciding whether injunctive relief was necessary, its ultimate findings regarding the risk of a return to the unlawful policies, the effectiveness of the AMA's discontinuance or voluntary cessation, and the character of the past violations, without question satisfy the proper standard. W.T. Grant, 345 U.S. at 633. None of the objections the AMA raises on appeal undercuts the district court's decision to grant an injunction. That the AMA feels an injunction is not necessary (or for that matter, that even we may have felt the same had we considered the case as an original matter), is not the appropriate test. That call was for the district court to make. Id. Because the district court did not abuse its discretion, we uphold its decision to award injunctive relief. [FN5]

FN5. Based on the language in section 16 that equitable relief is available "when and under the same conditions and principles as injunctive relief . . . is granted by courts of equity. . . .," the AMA makes

a passing argument, buried in two of its 67 footnotes (two footnotes, incidentally, that are separated by seven pages of text) that the district court erred by not requiring the plaintiffs to meet all the requirements for an injunction that traditional equity jurisprudence imposes. The AMA does not bother to say what those traditional equitable requirements are, in the case of a permanent injunction, except to say that the plaintiffs had to show they had no adequate remedy at law. Nor does the AMA cite any cases concerning the propriety of a permanent injunction under § 16.

The Supreme Court has stated § 16 invokes "traditional equitable principles." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 130, 89 S. Ct. 1562, 23 L. Ed. 2d 129 (1969); see also *Roland Machinery Co. v. Dresser Industries, Inc.*, 749 F.2d 380, 386 (7th Cir. 1984). Scholarly comment has echoed this theme. *E.g.*, 2 P. Areeda and D. Turner, *Antitrust Law* § 312d (1978); Easterbrook and Fischel, *Antitrust Suits by Targets of Tender Offers*, 80 Mich.L.Rev. 1155, 1168-69 (1982). Section 16's language indicates that traditional equity principles should apply. But while it is true that the district court stated that the plaintiffs did not have to meet all the traditional equitable requirements for an injunction, we are not convinced that this misstatement affected the court's analysis. The important point is that equitable relief is discretionary, and not automatically available to an injured plaintiff. See Areeda & Turner, *supra*, § 312d at 39. The district court did exercise discretion and did not automatically grant the plaintiffs an injunction. The court carefully weighed the AMA's conduct, the likelihood it would recur, the harm it caused and might in the future cause, and we believe, implicitly in all this, the relative hardships to

> the parties of granting an injunction. *See* 671 F. Supp. at 1484-88.
>
> It is true that the district court did not specifically find that the plaintiffs had no adequate remedy at law. The AMA baldly asserts that damages would have been adequate, but does not mention how. At any rate, at this stage in the case, we are not inclined to reverse the district court's careful decision based on an underdeveloped argument that the AMA did not even deem worthy of including under a separate heading in the text of its brief.

Anticipating this negative (for it) result, the AMA makes a last-ditch perfunctory argument. It attacks the injunction, arguing that it is unnecessarily overbroad, purports to award classwide relief in a case that was never certified as a class action, and "implicate[s] the AMA's rights under the First Amendment." None of these arguments are convincing.

[13] True enough, as the AMA observes, an injunction in a private antitrust suit should award a plaintiff injunctive relief "only to the extent necessary to protect it from future damage likely to occur if the defendant continues the unlawful antitrust conduct." *Ohio-Sealy Mattress Manufacturing Co. v. Sealy, Inc.*, 669 F.2d 490, 495 (7th Cir. 1982). But beyond this general principle, the AMA does not make any genuine argument that the injunction is overbroad. Instead, it simply asserts that the primary beneficiaries of the district court's order, insofar as it requires the order to be mailed to every AMA member, that it be published in the *Journal of the American Medical Association*, and that the AMA revise a national ethical publication, are the some 30,000 chiropractors in the nation as a whole who were not parties to this case. Doubtless, these other chiropractors may benefit from the mass mailing

and publication required by the district court's order. But this does not necessarily make the injunction overbroad.

The AMA's suggestion that the publications and mailings should have been limited to the four communities in which the individual plaintiffs practiced unnecessarily limits the relief, and ignores the public interest served by private antitrust suits. Such suits can effectively open competition to a market that was previously closed by illegal restraints. *National Society of Professional Engineers*, 435 U.S. at 698, 98 S. Ct. at 1368; *see also International Salt Co. v. United States*, 332 U.S. 392, 401, 68 S. Ct. 12, 17, 92 L. Ed. 20 (1947). Relief here is provided not only to the plaintiff chiropractors, but also in a sense to all consumers of health care services. Ensuring that medical physicians and hospitals are free to professionally associate with chiropractors (e.g., by the publication and mailing of the order to AMA members), likely will eliminate such anticompetitive effects of the boycott as interfering with consumers free choice in choosing a product (health care provider) of their liking. In this way competition is served by the injunction. In short, the injunction, as designed by Judge Getzendanner, reasonably attempts to eliminate the consequences of the AMA's boycott, and we will not disturb it. *National Society of Professional Engineers*, 435 U.S. at 698. [FN6]

FN6. For the same reason, we do not view the district court's injunction as improperly awarding classwide relief where no class was certified. The AMA's argument in this regard is just a rephrasing of its argument that the injunction is overbroad.

Finally, we reject the AMA's hint ("argument" seems too generous when the AMA's claim comprises but one paragraph of a 77-page brief, Max M. v. New Trier High School District No. 203, 859 F.2d 1297, 1300 (7th Cir. 1988))

that the district court's order somehow infringes on the AMA's First Amendment rights. We think the injunction as written is sufficiently tailored to avoid constitutional objection. As the Supreme Court has stated:

> [w]hile the resulting order may curtail the exercise of liberties that the [defendants] might enjoy, that is a necessary and, in cases such as this, unavoidable consequence of the violation. . . . The First Amendment does not 'make it . . . impossible ever to enforce laws against agreements in restraint of trade. . . .' *Giboney v. Empire Storage and Ice Co.*, 336 U.S. 490, 502, [69 S. Ct. 684, 691, 93 L. Ed. 834 (1949)]. In fashioning a remedy, the District Court may, of course, consider the fact that its injunction may impinge upon rights that would otherwise be constitutionally protected, but those protections do not prevent it from remedying the antitrust violations.

National Society of Professional Engineers, 435 U.S. at 697-98, 98 S. Ct. at 1368-69. That the injunction requires the AMA to publicize and mail copies of the order to AMA members, among other things, does not render it unconstitutional. The district court's form of injunction and method of ensuring its publication (and thus its efficacy) was a reasonable attempt at eliminating the consequences of the AMA's lengthy, systematic, successful, and unlawful boycott.

IV.

Plaintiffs' Cross-Appeal

Plaintiffs filed a cross-appeal challenging the judgments for defendants JCAH and ACP. With respect to JCAH, plaintiffs advance two separate theories of liability. First, they allege that JCAH unlawfully conspired with the AMA and participated in the AMA's boycott of chiropractors. Second, plaintiffs contend that JCAH, as a membership trade association, acted as a conspiracy each time it promulgated industry standards, and thus violated the antitrust laws in its own right. As to the latter theory of liability, plaintiffs assert that they raised it before the trial court, but that the court never ruled on it. JCAH does not contest this summarization of the events in the district court, and we accept it. Plaintiffs' theory against ACP also is two-fold. They first contend that ACP also participated in the AMA's boycott. Second, they charge that ACP is a member of the "continuing conspiracy that is the JCAH." None of plaintiffs' arguments are persuasive.

Following the first trial in this case, JCAH and ACP appealed the denial of their motions for a directed verdict. We affirmed the denial of those motions, explaining that the evidence was sufficient to permit, but not require, a jury (or, as it turned out, the trial court) to conclude that the defendants JCAH and ACP knew that concerted action in a scheme was contemplated and invited, and that both acquiesced and participated in that scheme. *Wilk I*, 719 F.2d at 233. This would have permitted a finding of liability, we reasoned, citing *Theatre Enterprises Inc. v. Paramount Film Distributing Corp.*, 346 U.S. 537, 540, 74 S. Ct. 257, 259, 98 L. Ed. 273 (1954); *Interstate Circuit Inc. v. United States*, 306 U.S. 208, 226-27, 59 S. Ct. 467, 474-75, 83 L. Ed. 610 (1939).

Following *Wilk I*, the Supreme Court decided two cases, which the district court in the second trial held clarified and limited the cases relied upon in *Wilk I*. These cases were *Monsanto v. Spray-Rite Service Corp.*, 465 U.S. 752, 104 S. Ct. 1464, 79 L. Ed. 2d 775 (1984), and *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986). In *Monsanto*, the Court held that, to survive a summary judgment motion, an antitrust plaintiff needed evidence tending to "exclude the possibility" that the alleged conspirators were acting independently, *id.* at 764, 104 S. Ct. at 1471, and that the plaintiff must present "direct or circumstantial evidence that reasonably tends to prove" that the alleged conspirators "'had a conscious commitment to a common scheme designed to achieve an unlawful objective.'" *Id.*, quoting *Edward J. Sweeney & Sons v. Texaco, Inc.*, 637 F.2d 105, 111 (3d Cir. 1980), *cert. denied*, 451 U.S. 911, 101 S. Ct. 1981, 68 L. Ed. 2d 300 (1981). *Matsushita* reaffirmed that holding. There, the Court stated "conduct that is as consistent with permissible competition as with illegal conspiracy does not, without more, support an inference of conspiracy." 475 U.S. at 597 n. 21.

Applying *Monsanto* and *Matsushita*, the district court analyzed plaintiffs' claims to determine whether or not each defendant's own conduct showed membership in the AMA's conspiracy. 671 F. Supp. at 1489. [FN7] We review each defendant separately. Again, because the district court adequately set forth the facts, we only summarize them here.

FN7. The district court also held that even if JCAH were acting independently of the AMA boycott, its members (e.g., the AMA) were not responsible for the actions of JCAH. 671 F. Supp. at 1491-92. On appeal, plaintiffs tell us that this was unnecessary, and actually confused their asserted theory that

JCAH was an unlawful conspiracy in its own right. Thus, we do not pass on the propriety of the district court's ruling in this regard.

A. *JCAH*

JCAH is a not-for-profit corporation established for the purpose of setting standards and conducting health care accreditation programs in conjunction with those standards. JCAH's members include the AMA, ACP, the American College of Surgeons, the American Hospital Association, and the American Dental Association. It is governed by a board of commissioners. Twenty-one commissioners are appointed by the various members, who then appoint one public commissioner. The AMA is one of JCAH's two "dominant members" (this characterization being based solely on the number of commissioners each member is allotted).

Participation by hospitals in the JCAH's accreditation program was voluntary. Nevertheless, accreditation was important to a hospital and "loss of accreditation would be devastating." *Id.* at 1490. Since before 1958, JCAH had standards providing that hospital medical staffs were to be limited to fully licensed physicians (this was liberalized in 1970 to include dentists). *Id.*

In 1964, JCAH's director stated, in a national newsletter, that JCAH viewed chiropractors as cultists, and that hospitals that encouraged such cultists to use their facilities in any way would "very probably be severely criticized and lose [their] accreditation." Despite the similarity of this statement to later AMA efforts, the district court found there was no direct evidence that JCAH was acting in concert with the AMA with regard to this statement or its distribution; thus, it concluded this action was independent.

In 1970, JCAH completed a revision of its standards and published an accreditation manual for hospitals. The manual included "Standard X" (which was drafted by the AMA). Standard X provided that the governing board of each hospital had to assure that medical staff members practiced in an ethical manner. The accreditation manual included a source reference to the AMA's Principles. The district court found that the uncontradicted testimony was that JCAH's board of commissioners never discussed the subject of chiropractic in connection with the accreditation manual. It further found that no chiropractor participated in the accreditation manual's revision process despite the opportunity to participate. *Id.* Based on these findings, the court concluded there was no evidence that JCAH adopted Standard X in connection with chiropractors or to further the AMA's boycott. And while JCAH letters responding to inquiries from hospitals about the role of chiropractors throughout the 1970s did indicate that JCAH would withdraw accreditation of a hospital that had chiropractors on its medical staff or that granted privileges to chiropractors, the district court found these letters were completely consistent with the then-existing accreditation standards, and were "not convincing evidence that JCAH had joined the conspiracy against chiropractors." *Id.*

Finally, in 1977, JCAH revised its standards to provide that medical staff membership was to be limited "unless otherwise provided by law" to fully licensed physicians and dentists. References to the AMA's Principles were deleted. So from 1977 on, JCAH's position on chiropractors was that, as limited licensed practitioners, they could be included on medical staffs, if permitted under local law. In 1980, JCAH amended the accreditation manual by deleting Standard X.

Based on these findings, the district court found that all JCAH undertook all action from 1964 through 1980 independently of the AMA boycott. Further support for its

conclusion was the fact that JCAH's standards were largely consistent with federal law. *Id.*

Likewise, the district court found that the 1983 revisions of the JCAH standards were independent of the AMA boycott, and that the 1983 revisions were not evidence that the conspiracy against chiropractors continued into 1983. Ultimately, JCAH standards were liberalized regarding admission to medical staffs and allowance of hospital privileges to limited licensed practitioners, including chiropractors. But the standard also required that each accredited hospital's medical staff have an executive committee, the majority of which had to be medical and osteopathic physicians. (This, according to plaintiffs, is evidence that the conspiracy against chiropractors continued into 1983.)

In 1983 the AMA participated in the JCAH standards revision process. That process began in 1982 with recommendations from JCAH staff and the JCAH standard-survey procedures committee. The early recommendations were that each hospital be permitted to decide for itself, under applicable state law, which licensed health care providers would be allowed hospital privileges and medical staff membership. After initially supporting this approach, AMA members and other medical societies which wanted to ensure medical and osteopathic physician control of the medical staff and patient care in hospitals criticized the AMA. Feeling the heat of their members' criticism, the AMA changed its position and supported revisions which would ensure such control. In late 1983, JCAH adopted new standards which included the mandatory, medical physician-dominated executive committee concept.

According to the district court, the evidence supported the conclusion that JCAH members were acting to ensure that the responsibility for patient care in acute care hospitals

remained in the hands of medical and osteopathic physicians, and that this was an appropriate goal for JCAH. Patients in acute care hospitals are generally the very sick or in need of surgery. They are patients who require treatment with drugs or surgery -- i.e., treatment by fully licensed physicians (that chiropractors may not perform). This led the court to conclude that "[t]he evidence supports no conclusion other than that patient care in acute care hospitals, and the medical staffs of acute care hospitals, ought to be under the control of fully licensed physicians rather than limited licensed practitioners. I am persuaded that the JCAH members were not acting to prevent chiropractors from being admitted to hospitals or obtaining hospital privileges." 671 F. Supp. at 1493. [FN8]

> FN8. The court went on to observe that under current JCAH standards, hospitals could grant chiropractors medical staff membership, clinical privileges, admission privileges, and access to diagnostic services without fearing loss of JCAH accreditation. Authority for making individual medical staff appointments now rests with the individual hospital's governing board.

Because the court found that JCAH's acts before the 1983 revisions were independent of the AMA boycott, and that the 1983 revisions were not evidence that the conspiracy against chiropractors continued into 1983, it concluded that plaintiffs failed to prove that JCAH was a member of the conspiracy. Id. at 1494.

1. JCAH as Conspiracy

[14][15] Plaintiffs' first theory on appeal is that JCAH, as a trade association, "acts as a conspiracy or combination every time it promulgates industry standards [which unreasonably restrain competition]." But a trade association

is not, just because it involves collective action by competitors, a "walking conspiracy." *Consolidated Metal Products, Inc.*, 846 F.2d at 293-94. There is no evidence that JCAH's accreditation program "is merely a ploy to obscure a conspiracy" against chiropractors. *Id.* at 294. And plaintiffs' arguments for a separate antitrust violation with respect to JCAH standing alone are unpersuasive.

The most serious problem with plaintiffs' theory is that they did not prove any actual or threatened antitrust injury directly traceable to the alleged antitrust violation which would be redressed by the issuance of an injunction against JCAH. *See Cargill, Inc. v. Monfort of Colorado Inc.*, 479 U.S. at 122, 107 S. Ct. at 495. Thus, even if this particular claim was not expressly addressed by the district court, plaintiffs' claim still must fail. In support of their contention that they suffered actual injury, plaintiffs offer "evidence" of examples of when each plaintiff was denied privileges or medical staff membership at certain hospitals. But after thoroughly reviewing the record, we conclude these examples do not show any connection to JCAH or its Standard X. (Jt.App. 13-14; 15-17; 89-100; 181; 182-87; 190-91; 380-81; 420; 672-81; 773-74; 851; and 934-35.) Because we find no antitrust injury occurred as a result of the 1970 Standard X, we necessarily conclude that there was no continuing JCAH boycott as a result of the revisions in 1983. [FN9]

FN9. Plaintiffs claim, for the first time in their reply brief, that the 1983 standards themselves violate the antitrust laws. The district court, however, stated that plaintiffs were not claiming that the 1983 JCAH standards violated the antitrust laws. 671 F. Supp. at 1492. Whether they did or did not raise the issue in the district court, there is no question that the plaintiffs' initial appellate brief did not raise this issue. Rather, plaintiffs argued that "The JCAH 1983 Revisions Continue[d] The Boycott." In this regard

they stated, "only one conclusion is possible: the JCAH M.D. domination standard *perpetuates* the boycott" (emphasis added). We think it plain that plaintiffs made their claim that the 1983 revisions themselves were unlawful for the first time on reply. We thus will not address the argument. *See Gold v. Wolpert*, 876 F.2d 1327, 1331 n. 6 (7th Cir. 1989).

2. JCAH as Member of the AMA Boycott

[16] Plaintiffs' second theory of antitrust liability against JCAH contends that JCAH was a member of the AMA's boycott. In this regard, plaintiffs contend that JCAH knew the AMA boycott was contemplated and that it acquiesced and participated in that scheme. As stated above, the *Monsanto* and *Matsushita* cases hold that to establish liability under this theory, there must be evidence that at least tends to exclude the possibility that the alleged conspirators were acting independently, rather than pursuant to "'conscious commitment to a common scheme designed to achieve an unlawful objective'," *Monsanto*, 465 U.S. at 764, 104 S. Ct. at 1471, quoting *Edward J. Sweeney & Sons*, 637 F.2d at 111. Plaintiffs, however, argue that *Monsanto* and *Matsushita* are inapplicable to this case because here we are dealing with a horizontal combination, and because there is "direct evidence" of a conspiracy in this case. We agree with the district court, however, that this case should be governed under the standards set forth in *Monsanto* and *Matsushita*. We have stated before, "[t]he actual label placed on the conspiracy is a 'pedantic distinction,' as the Monsanto standard applies regardless of which label is attached." *Valley II*, 822 F.2d at 660 n. 5. And plaintiffs point to no "direct evidence" of the conspiracy.

At best, plaintiffs make only a perfunctory argument that JCAH knowingly adhered to and participated in the AMA's unlawful boycott. Nowhere do they attempt to show

just how the district court made erroneous findings of fact. Rather, they point to the fact that JCAH adopted Standard X (after being manipulated by the AMA in doing so) to establish JCAH's participation in the boycott. But the district court found that JCAH's board of commissioners never discussed the subject of chiropractic, and that the subject was never raised in connection with the 1970 revisions of the accreditation manual. It also found that no chiropractor participated in the revision process despite having an "extensive opportunity" to do so. Thus, the court held "[there] was no evidence that JCAH adopted Standard X in connection with chiropractors or in furtherance of the AMA boycott." 671 F. Supp. at 1490. Plaintiffs' urgings to the contrary are nothing but a bald invitation to substitute our judgment for the district court's. Consistent with our prior treatment of this issue in *Wilk I*, 719 F.2d at 233, the evidence may have been sufficient to find that JCAH participated in the conspiracy, but it did not require such a finding. The district court was entirely within its right to find no conspiracy between JCAH and the AMA.

As evidence of JCAH's participation in the conspiracy, plaintiffs also point to the district court's finding that JCAH cooperated with the AMA in connection with the distribution of an article titled "The Right and Duty of Hospitals to Exclude Chiropractors from Hospitals." Apparently, they believe this carries the day in establishing JCAH's participation in the boycott. We disagree. As the district court found, the JCAH's use of the cited article was in connection with inquiries from hospitals about the role of chiropractors in hospitals. 671 F. Supp. at 1490. The court also found that the JCAH letters were "completely consistent with the then-existing accreditation standards." *Id.* We thus agree with the district court that this was "not convincing evidence" that JCAH participated or joined in the AMA's conspiracy against chiropractors. *Id. Cf. Monsanto*, 465 U.S. at 762, 104 S. Ct. at 1470 (communication about prices and

marketing strategy does not alone show that distributors are not making independent pricing decisions). [FN10]

> FN10. Plaintiffs make one additional claim. This case, they tell us, fits neatly within the framework of *American Society of Mechanical Engineers, Inc. v. Hydrolevel Corp.*, 456 U.S. 556, 102 S. Ct. 1935, 72 L. Ed. 2d 330 (1982). They assert that because the trial court found the AMA manipulated the JCAH and caused it to adopt Standard X (as well as circulating the AMA's "Right and Duty of Hospitals to Exclude Chiropractors"), that JCAH was liable because it allowed itself to be manipulated and used as a mechanism through which the AMA enforced its anti-competitive scheme. Plaintiffs cite *Hydrolevel* in the portion of their argument dealing with JCAH's alleged knowing adherence and participation in the AMA's boycott. But *Hydrolevel* does not address the conscious parallelism issue. *Hydrolevel* speaks of an association's liability in its own right, not as a member of another's unlawful conspiracy. We thus believe *Hydrolevel* is inapplicable to this case.

B. *ACP*

The analysis and outcome would be much the same for ACP as for JCAH, at least so far as its alleged participation in the AMA's boycott is concerned. ACP's alleged membership or participation in the AMA's unlawful boycott, for example, is also judged under the *Matsushita* and *Monsanto* standards. Here, though, we must digress briefly to address a problem with plaintiffs' argument. Their claims in this respect seem at best to be confused. In their opening brief, they refer to the ACP's participation in "the boycott," and argue that the district court's finding that the ACP did not participate in any boycott of chiropractors is clearly erroneous. The district court's findings in this regard

concern whether or not ACP was a member of or participated in the AMA's conspiracy. 671 F. Supp. at 1471, 1489, 1494-96. It is obvious from the district court's opinion, and from plaintiffs' opening brief, that "the boycott" referred to is the AMA's unlawful boycott. But in their reply brief, plaintiffs say it is "irrelevant" whether or not ACP conspired with the AMA. In other words, they are arguing that the district court's finding that ACP was not a member of the AMA's boycott, 671 F. Supp. at 1494-96, is not at issue on this appeal. We will take them at their word; that issue is now foreclosed against them.

Apparently, then, plaintiffs are claiming, as they did with JCAH, that the ACP as a membership association engaged in concerted activity through various acts. That is, the ACP is liable under § 1 of the Sherman Act in its own right. Plaintiffs also present a second theory of liability: that the ACP, as a member of the JCAH, is liable for the unlawful acts of that organization because it knowingly participated in and ratified those acts.

1. ACP as a Conspiracy

There is no evidence that ACP itself engaged in an unlawful boycott of chiropractors. Plaintiffs point to the ACP's bylaws which provided that the purpose of the ACP included "preserving the history and perpetuating the best tradition of medicine and medical ethics." Because of the fact that many of the ACP's members were also AMA members, plaintiffs argue that this veiled reference to ethics somehow furthered an ACP boycott. But the ACP never adopted the AMA's Principles (including former Principle 3), and never required its members to subscribe to those principles. 671 F. Supp. at 1494. Also, the ACP never had a code of ethics. In 1984 it published the American College of Physicians Ethics Manual. But this was not a code or set of regulations. Rather, it was an effort to address major contemporary

issues confronting all physicians and merely attempted to stimulate debate on medical ethics. The manual stated nothing about chiropractic or about what remedies are or are not "scientific." Indeed, as the district court found, the manual appears to leave the individual physician free to make his own judgment as to the kinds of treatment he should participate in and in his relations with other licensed health practitioners. 671 F. Supp. at 1494.

The plaintiffs rely on two additional documents to establish an ACP boycott. The first grew out of a September 1978 meeting of the ACP's board of governors. (The board of governors was not the ACP's policymaking body.) The Board at that meeting accepted a report by an ad hoc committee appointed to suggest what might be done to promote the ACP's policy toward chiropractic. According to the district court, the minutes of that meeting reflect that:

> The committee agreed unanimously that ACP should be concerned about and oppose any action which would include chiropractic among the scientifically-based modes of medical care and which would give chiropractors direct access to the diagnostic facilities of hospitals.

671 F. Supp. at 1495. Plaintiffs also point to a resolution adopted by the board of governors which provided, among other things:

> (2) the governors should remain alert to efforts of chiropractors to gain access to radiographic and clinical laboratory diagnostic facilities in their regions and keep ACP headquarters informed of such developments;

******

(8) the governors should alert colleagues in other disciplines to the efforts of chiropractors to gain access to radiographic and clinical pathology diagnostic facilities; and

(9) the governors and the college members in their regions should discuss these matters with their county and state medical societies and with their representatives to the house of delegates of the AMA.

671 F. Supp. at 1495-96.

Although the district court found that many parts of the resolution related to matters protected under the Noerr-Pennington doctrine, not everything included was protected. (This is not at issue on appeal.) What is important is that the district court found that the resolution contained no call for the participation of ACP or its members in the AMA's boycott against chiropractors, "or [in the] ACP's own boycott." 671 F. Supp. at 1496. Continuing, the court explained "[m]oreover, the resolution was never implemented . . . and there is no evidence that ACP members were called upon to cooperate in effectuating ACP's 'policy' on chiropractic." *Id.* Plaintiffs do not show how the district court's findings are clearly erroneous; rather, they just interpret the document differently. It is well established by now, however, that we do not substitute our view of the facts for the district court's on appeal. After reviewing the evidence, we are not left with the "definite and firm conviction" that the district court made a mistake in interpreting this evidence. *Anderson v. City of Bessemer City*, 470 U.S. 564, 573, 105 S. Ct. 1504, 1511, 84 L. Ed. 2d 518 (1985).

Plaintiffs also point to a joint document in which the ACP participated, titled "Status Report on Chiropractic Lawsuits" to establish an ACP conspiracy. The report was distributed to ACP members. It does contain an admission that Principle 3 forbade association with chiropractors. But, as the district court explained, this admission was irrelevant as to ACP which had not adopted the AMA's Principles, and which did not have a medical ethic similar to Principle 3. We agree. Again, plaintiffs just offer their different interpretation of the document, which has never been enough to carry the day when reviewing a district court's factual determinations. We see no error. [FN11]

FN11. Plaintiffs also argue that the district court erroneously "excluded evidence [which] proves ACP's knowing intent to exclude chiropractors." (Plaintiff's reply br. at 23.) What plaintiffs are getting at is that certain evidence was held by the district court to be protected under the Noerr-Pennington doctrine. The first involved a letter written to a governmental agency (the National Institute of Neurological Diseases and Strokes (NINDS)) in connection with a government project (the study of chiropractic). Plaintiffs claim this was not protected under the Noerr-Pennington doctrine because blind copies were sent to the AMA's Committee on Quackery and other medical societies. They ignore the fact, however, that the district court made an alternative holding with respect to this letter. It stated that even if the letter was not protected, it was obvious that it expressed only the author's own opinion as to what action the ACP's board of regents (its policy-making body) might take in the future, and that it was not the act of the ACP endorsing the AMA chiropractic policy statement. The court also found there was no evidence that ACP had knowledge of the activities of the Committee on

Quackery. Thus, we do not need to address whether or not this document was protected under the Noerr-Pennington doctrine, as the alternative ground is both sound and unchallenged.

Plaintiffs make two perfunctory and undeveloped contentions with regard to "exclusion" of "boycott activity." But neither of these amounts to an "argument" under Fed. R. App. P. 28(a)(4). Thus, we will consider neither.

2. ACP Participation in JCAH's Conspiracy

Finally, plaintiffs contend that ACP is a member of "the continuing conspiracy that is the JCAH." But since we have held JCAH did not violate the antitrust laws, ACP could not be liable for participating in JCAH's acts. Thus, plaintiffs' theory that ACP is liable for participating in JCAH's conspiracy fails.

V.

Conclusion

We affirm the district court's finding that the AMA violated § 1 of the Sherman Act by conducting an illegal boycott of chiropractors, and the district court's decision to grant an injunction against the AMA. In finding liability, the court did not improperly rely on evidence of conduct protected by the Noerr-Pennington doctrine. The district court's factual findings supported its finding that the AMA's boycott was illegal under the rule of reason, and those findings were not clearly erroneous. The district court also did not clearly err in finding that the AMA did not meet its burden of proving its patient care defense, and in finding that the AMA's boycott caused the plaintiffs past injury and the threat of future injury. The court did not abuse its

discretion in imposing an injunction on the AMA. The court's factual findings supported its exercise of equitable discretion, and the injunction was not overbroad.

We also affirm the district court's findings that JCAH and ACP did not participate in the AMA's boycott, or in any other way violate § 1 in their activities concerning chiropractors. The plaintiffs' theory that JCAH itself conspired by setting standards fails because the plaintiffs failed to prove that the JCAH's actions caused them any actual or threatened injury. The court's finding that JCAH did not participate in the AMA's conspiracy was not clearly erroneous. The plaintiffs have waived any contention that ACP participated in the AMA's conspiracy by claiming that any such participation was "irrelevant." The district court did not clearly err by finding that ACP did not conduct its own conspiracy, and since JCAH did not violate § 1, ACP could not be liable for participating in JCAH's actions.

The district court's decision is

AFFIRMED.

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In The Supreme Court of the United States

AMERICAN CHIROPRACTIC ASSOCIATION, INCORPORATED, a non-profit corporation, *et al.*,

Petitioners,

v.

TRIGON HEALTHCARE, INCORPORATED, *et al.*,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

APPENDIX A (VOL. II OF III) TO
PETITION FOR WRIT OF CERTIORARI

George P. McAndrews
Counsel of Record
Steven J. Hampton
Patrick J. Arnold, Jr.
Sharon Hwang
James P. Murphy
Peter J. McAndrews
Ronald A. Dicerbo
MCANDREWS, HELD & MALLOY, LTD.
34th Floor
500 West Madison Street
Chicago, IL 60661
(312) 775-8000

Thomas R. Daly
ODIN, FELDMAN, & PITTLEMAN, P.C.
9032 Lee Highway
Suite 1100
Fairfax, VA 22031
(703) 218-2100

William G. Shields
THORSEN & SCHER
3810 Augusta Ave.
Richmond, VA 23230
(804) 359-3000

Counsel for Petitioners

THE LEX GROUP ♦ 1108 East Main Street ♦ Suite 1400 ♦ Richmond, Virginia 23219
(804) 644-4419 ♦ (800) 856-4419 ♦ Fax: (804) 644-3660 ♦ www.thelexgroup.com

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ARTICLE: EXCLUSIVE JOINT VENTURES AND ANTITRUST POLICY Herbert Hovenkamp *

* Ben V. & Dorothy Willie Professor of Law, the University of Iowa. The author was consulted in two decisions discussed in this article: by the state Attorneys General in Hartford Fire Ins. Co. v. California, 113 S. Ct. 2891 (1993); and by Dean Witter in SCFC ILC, Inc. v. VISA U.S.A., Inc., 819 F. Supp. 956 (D.Utah 1993), rev'd, 36 F.3d 958 (10th Cir. 1994).

SUMMARY:

... A joint venture is created whenever two or more economic actors ("firms")join together to engage in some economic activity .... The Antitrust Legacy Concerning Joint Venture Exclusion ... For example, the VISA/Dean Witter case is an antitrust dispute that arose when Dean Witter, the owner of Discover Card, was denied its request to join the VISA joint venture If the joint venture as a unit lacks market power, the simple failure to maximize is not ordinarily an antitrust concern... In the VISA case, for example, the effect of the exclusion was to prevent the introduction of Dean Witter's VISA/Discover Card package, and existing Visa members from issuing proprietary cards of their own -- but this product exclusion was accomplished simply by excluding Dean Witter from the Visa joint venture altogether .... Economically, market power is a firm's ability to profit by raising price above marginal cost .... Does any

aspect of the challenged venture or the exclusion rule or practice being challenged threaten to reduce output or raise prices in some properly defined relevant market? In addressing this question, the court must first define relevant markets under ordinary antitrust principles for any market level at which competition might be threatened ....

TEXT:
[*2]

I. Introduction

A joint venture is created whenever two or more economic actors ("firms")join together to engage in some economic activity, nl **[*3]** The firms participating in a joint venture need not be competitors, and often they are not, but antitrust liability generally requires that they be either competitors or potential competitors.

Joint ventures engage in a wide array of economic or productive activities: research and development, exploration for resources, advertising and promotion, production, distribution, or creation of the market. They may be legally organized as partnerships or corporations, n2 or they may simply be private contractual agreements, n3 The legal form of organization is seldom relevant to the analysis presented here. The mechanism by which decision-making occurs is often relevant, however, and the legal form may influence the form of decision-making.

A joint venture exists when two conditions are satisfied: (1) two or more firms join together to produce one or more of the inputs n4 that go into their production or distribution process, but (2) this union is something less than the formation of a single firm. Joint ventures' principal relevance to antitrust policy is that, while they often result

in lower costs or improvements in product quality or distribution, they can also threaten competition.

Most joint ventures are efficient. However, that fact is not sufficient for antitrust to withhold its concern. If a venture produces no efficiency gains whatsoever but yields only injury to competition, then antitrust policy condemns it automatically as illegal per se. More common, however, is the venture that produces efficiency gains but also yields opportunities for anticompetitive [*4]behavior. In that case, antitrust policy makers must devise administrable rules that permit the efficiency gains to occur while reducing or eliminating the opportunities for anticompetitive behavior. Alternatively, if the opportunities for anticompetitive behavior cannot be eliminated, the antitrust policy maker must decide if the welfare gains are sufficient to justify the loss of competitive incentives.

Joint ventures raise antitrust concerns when they facilitate the exercise of market power, or threaten to do so. n5 As a general matter, the exercise of market power can come about by collusion or by exclusion. In a collusive arrangement, venturers who have market power collectively reduce marketwide output and raise the price of some product or service that the venture controls. The antitrust remedy depends on the degree of the competitive threat, the legitimacy and efficiency potential of the underlying venture itself, and the essentiality of the price or output fix to the functioning of the venture. For example, if a court finds that the "joint venture" itself is nothing more than a front for naked collusion, it is likely to condemn the entire venture as illegal per se. The Supreme Court did this, erroneously, in its very first antitrust decision on the merits, the Trans-Missouri Freight Association case. n6 The Court

saw a joint operating agreement among railroads, having great efficiency potential, as nothing more than a cartel. It granted the government's request to dissolve the entire arrangement. **[*5]**

If the venture is obviously efficient but the price fix or output restriction seems unnecessary to the functioning of the venture, then the court may appropriately enjoin the price fix or output restriction without touching the venture itself. For example, in National Collegiate Athletic Association ("NCAA") the Supreme Court enjoined the defendant from limiting the number of times that college football teams televise their games; but no one suggested using the antitrust laws to destroy the entire joint venture producing NCAA football, n7 If the venture is obviously efficient and the price fix or output restriction is an integral part of the venture, then the court may have to perform some fairy delicate balancing. For example, in the Broadcast Music decision, it permitted a joint venture that clearly had some market power to use a blanket license scheme that effectively involved artists and other performance right holders' fixing the prices of their intellectual property, n8 The Court was persuaded that, given the transaction costs of any realistic alternative, the joint venture resulted in greatly reduced prices or higher output, notwithstanding the price fixing, n9

Joint ventures can also exercise market power by exclusion, which occurs when existing venturers refuse to admit a firm that wishes to join, or expel a firm that wishes to stay in the joint venture. Anticompetitive exclusion can also occur when the venture disapproves a product or service that one group of venturers wishes to provide but that a decisive number nl0 of the venture's decision makers

prefer not be provided by any [*6] venture member. We refer to the first of these forms of exclusion as "member exclusion" and the second as "product exclusion." nl 1 Some joint ventures do both at the same time.

In exclusion cases antitrust policy has the difficult job of determining how the exclusion operates within the overall plan of the joint venture. An exclusion may be nothing more than a cartel facilitator. Cartels work successfully only if they can maintain their market shares, and member exclusion may be a method by which colluding venturers keep others from cutting into their markets. For example, if venturers A, B, and C have developed a process that gives them a cost advantage over rivals X, Y, and Z, the first three firms may be in a position to collude. But if X, Y and Z are permitted to join, there may be as much competition as there was before the venture was formed. Exclusion of X, Y and Z may relegate the excluded firms to the position of a high-cost fringe, perhaps having only a modest impact on the cartel profits.

Product exclusion can perform the same function. For example, firms fixing the price of steel conduit (or operating in an oligopoly) may preserve market dominance by excluding a rival product, plastic conduit, from the market or limiting its growth, n12 In order to accomplish this, the firms need not exclude the maker or potential maker of plastic conduit from the venture; they need only exclude its product. Likewise, a collusive group of insurers offering policies providing fairly narrow insurance coverage may feel threatened by rival insurers who wish to offer broader coverage, which customers prefer. The dominant insurers may respond by using the venture to deny the rivals access to essential inputs, such as statistical data

necessary for determining risks, or reinsurance necessary for spreading risks, n13 Once again, the firms wishing to offer the alternative product need not be excluded from the venture; only the product itself need be excluded.

Joint venture "exclusion" thus refers either to decisions that exclude a member or applicant for membership, or to decisions that exclude a product. "Exclusion" also refers to decisions that [*7] remove a product from the market altogether, prevent its entry, limit its growth or raise its cost. For example, the defendants in the Allied Tube case conspired to set standards that encouraged local governments to write building codes prohibiting the use of the plaintiffs plastic conduit, n14 The success of this scheme did not require the defendants to convince every single local government or private contractor to avoid plastic conduit; they merely had to convince enough of them to slow or limit plastic conduit's growth potential. Likewise, the Visa joint venture n15 did not need to force the applicant, Dean Witter, out of the general purpose charge card market altogether; its exclusionary rule was profitable if it simply limited the extent to which Dean Witter could cut into the market shares of established Visa members. "Exclusion" thus refers both to rules that keep firms out of the market altogether, and to rules that make it more difficult for firms who are already in the market to grow. n16 Under the right circumstances, both kinds of exclusion injure competition and harm consumers.

The difficult problem for antitrust policy is that the very same exclusions that facilitate anticompetitive behavior may have been essential to create the incentives to form the venture in the first place. Firms invest in joint ventures in order to improve their own market position; if everyone in the market has an automatic right to join, then the incentives to form the venture are correspondingly reduced.

This article attempts to identify the appropriate concerns of antitrust policy for joint ventures that engage in either member exclusion or product exclusion. Many exclusions are competitive and may even be essential to the success of the venture or to guaranteeing incentives to create similar ventures in the future. At the same time, however, we fear joint ventures because they may facilitate the exercise of market power, and successful acquisition or exercise of market power often requires some kind of exclusion. For example, if applications for membership are numerous, the cartel that admits all applicants will not be [*8] able to reduce marketwide output, which is essential to successful collusion, n17

Given that a joint venture's exclusivity rules can work either benefit or harm, bona fide exclusions should be governed by a rule of reason. Although that premise seems uncontroversial enough, it has not always been so, and the courts have traditionally looked at exclusivity rules, particularly exclusive membership rules, with hostility. They have often been treated as illegal per se. n18

At the other extreme is the view that joint venture exclusion rules pose only the most modest of competitive threats, no greater than occurs when a single firm refuses to cooperate with a rival, n19 But if one of these views is too hostile, the other is too sanguine. Joint ventures are efficient to the extent that they bring together firms who can take advantage of scale economies or diverse specialties. But they also unite firms that [*9] have different incentives. A joint venture is not the same thing as a merger; it is composed of two or more different firms, each of which wishes to maximize its own profits, n20 Where the profit maximization goals of individual members coincide with maximization of returns to the venture as a whole, the venture for all practical purposes operates as a single firm. But where these goals differ, the venture may be more likely

to behave anticompetitively. To the extent joint ventures are composed of individual profit-maximizing entities, the incentives of members may deviate substantially from the best interests of the venture as a whole, with "best interests" defined as the outcome that maximizes venture-wide profits. To the extent this is true, the joint venture operates more as a cartel than as a single firm. n21

"Network" Joint Ventures

Writers sometimes speak of "network" joint ventures as if these were a distinct classification, n22 But economically speaking, a network joint venture is not very distinguishable from joint ventures generally. All successful, competitive joint ventures either reduce costs or shift demand. They reduce costs by achieving economies of scale or scope not readily available to the venturers acting individually. They shift demand by improving products or by introducing new products that have not been on the market previously. They can also reduce transaction costs and force the internalization of externalities, particularly when intellectual property rights are not adequate to prevent others from free riding, n23 **[*10]**

The "network" joint venture is one that operates in an area where joint production or distribution is said to be necessary before the product can even exist, at least in the form offered by the joint venture, n24 Associated Press, NCAA football, long distance telecommunications since the AT&T divestiture, automated bank teller ("ATM") networks, n25 and MasterCard or VISA are all network joint ventures in this sense. Associated Press is a consortium of newspapers who create news stories for each other. The NCAA is an association that creates, among other things, the game of college football, makes its rules, administers its schedules, and the like. Since it takes at least two teams to have a football game, in one sense the product being

produced, "NCAA football," could not exist without at least some joint activity, n26

But this observation adds very little to any conception of the network joint venture as special. Indeed, the statement is true only given the NCAA's own starting rules and assumptions as a premise -- for example, that each college campus can have only one football team. Under an alternative arrangement a single college could have multiple teams playing "intramural" football, or a multi-campus university such as the University of California could have games among its campuses (such as UCLA v. U.C. Berkeley). So collegiate football as we know it could not exist without the venture, but football itself in some alternate form might survive quite well. Likewise, the entire NFL could be owned by one very large firm. Thus, saying that "NCAA football" or "NFL football" could not exist without a joint venture is certainly true, but it is no different than saying that "GM-Toyota" would not exist without the General MotorsToyota joint venture.

Further, given today's telecommunications system in the United States, it is impossible to make a long distance call **[*11]** without the cooperation of the local operating companies plus one of the long distance carriers. This joint venture is very literally a "network." Calls are routed from the caller via her local operating company to the long distance carrier's transmission facilities, from there to the long distance carrier's reception facilities and then back into a different local system to the person being called. But, in the nature of things, a joint venture is not essential to the production of long distance telecommunications. Indeed, before the 1983 decree that broke up the telephone company, n27 first all and later most long distance calling was made within a single firm, AT&T. n28

The same is true of the bank card industry. "MasterCard" is a joint venture composed of numerous card issuing institutions, and the venture itself acts as a clearing house, or broker, enabling debits and cash to flow from the card holder's bank to the merchant's bank. n29 But the same activities can be performed by a single firm, as in the case of American Express or Discover.

The most meaningful understanding of a "network" joint venture is that it is a kind of joint venture that creates economies in the ongoing production or distribution of a product. Often a research or development joint venture concludes its work when a certain product or process has been developed. Individual firms then take over the business of manufacturing and marketing. Other joint ventures are temporary in the sense that, although they may involve production or distribution, their real purpose is to facilitate learning, n30

In the "network" joint venture, by contrast, ongoing production or distribution of the product is done more efficiently by **['12]** the venture than it could be done by each participant individually, given the way that production and the market are organized. Further, under existing technology or distribution modes, or under our existing system of property rights or firm ownership, this situation is stable. As a result, the venture has a quasi-permanent character. NFL football provides a good example. As long as we have football as we now know it, where individual teams are separately owned and controlled, where at least two teams are needed to play a game under a common set of rules and schedules, and where teams are expected to play through a field of opponents and ranked on the basis of their records, some kind of joint venture is essential to the production of professional football. One might conceive of a different world in which a single firm owned and managed all the teams. In that case, coordination of football would be

nothing more than a parent corporation's operation of its subsidiaries, and no joint venture would be necessary. One can generally say the same thing about the St. Louis railroad terminal facility, n31 Associated Press, n32 and ASCAP's blanket licensing arrangements covering performance rights, n33 Alternative regimes could exist in which (a) a single firm owned all the players and operated them within the firm, or (b) a regulatory agency imposed the coordination of inputs on the participants.

In sum, then, joint ventures are artificial devices that represent an efficient method of engaging in enterprise given a particular set of assumptions about property rights and ownership. Changes in the nature of property rights or the scope of the firms owning them, may make existing joint ventures unnecessary or may create a market for new ventures. The relevant antitrust policy questions must focus not on whether alternatives to the venture are theoretically possible, but on whether the existing venture restrains competition given the system of property rights that already exist.

Joint ventures are also a "market" alternative to regulation. The joint ventures in the Trans-Missouri Freight Association case, n34 the Terminal Railroad case, n35 and the case of the telephone ['13] company all illustrate this. The first two cases represent elaborate ventures among railroad companies to coordinate routing, scheduling, allocation of revenue as among shipping, receiving and intermediate carders, and access to common essential facilities such as terminal points. Eventually many of these decisions were transferred to a government regulatory agency, the Interstate Commerce Commission. n36 With respect to the telephone company the chronology is just the reverse. First there was a giant telephone company, AT&T, providing both local and long distance service to almost everyone but heavily regulated by the Federal

Communications Commission. Later joint ventures developed involving, first, competing long distance carriers, and then local operating companies and long distance carriers. These ventures became necessary after deregulation permitted competition and eventually broke up AT&T and separated its long distance and local networks, n37

Once again, however, the existence or dissolution of the joint venture results from public policy decisions respecting a prior allocation of property rights. If the regulatory or property rights regime changes, some existing joint ventures may disappear while new ones may come into existence.

The role of antitrust is not to tamper with the basic regulatory regime, n38 nor to change the allocation of property rights unless the current allocation is anticompetitive. Antitrust must seek out and condemn joint arrangements that injure competition -- that is, which reduce marketwide output or innovation below the competitive level. Further, antitrust must do this without causing substantial injury to the system of incentives that motivates firms to enter efficient joint ventures in the first place. For example, expansive use of per se rules would certainly reduce the opportunity for price fixing, but in the process such rules might condemn many ventures that are, on balance, efficient. **['14]**

II. The Structural Logic of Joint Ventures

The promise of joint ventures flows from one fact: ventures are able to expand markets more readily than single firms can. Ventures do this in a variety of ways: making a product more attractive, developing new products that would be difficult or impossible to develop without joint participation, reducing the costs of production or the costs of using the market, enabling firms to better capture the results of their innovations.

A. The Joint Venture and the Firm

The best way to assess the structure and appropriate scope of joint ventures is by comparing them with firms. The same factors that account for the nature and scope of the firm explain the nature and scope of a joint venture. A firm is an organization that makes many decisions about production or distribution. With respect to each, it weighs the incremental costs and benefits of purchase on the market against the incremental costs and benefits of internal production, selecting the alternative that promises to be most profitable, n39 As Ronald Coase and Oliver Williamson have noted, using the market is itself costly. One must seek out the optimal supplier, trust the supplier to produce efficiently and sell at cost, and negotiate a contract specifying all desired terms. The less certainty one firm has about others, the stronger the case for self production. If the costs of dealing with another firm, including uncertainty costs, exceed the costs of making the input for oneself, the firm will organize this activity inside the firm, rather than purchasing from without, n40

A firm's decision to create a joint venture with another firm or to join an existing venture is in principle no different. For any given input, the firm compares the cost of purchase on the **['15]** market, of self-production, or of joint

production with one or more other firms. Risk is simply one of the many costs that must be counted. To be sure, the decision may be complicated because participation in joint ventures involves elements of both self-production and contracting. Everything that makes markets expensive, such as the need to locate proper trading partners, to trust them, and to negotiate contracts with sufficiently detailed specifications and creating the proper incentives, can apply to the formation of joint ventures as well as to outright market purchases, n41 Further, since joint ventures involve production that is "internal" to the firm, although carried on jointly with others, they also involve problems of internal firm organization. Nevertheless, the combined costs of bargaining and organizing to a joint venture may be less than the costs of either a pure market purchase or of pure self-production. When they are, the profit-maximizing firm will choose the joint venture.

As a first cut, then, joint ventures are calculated to reduce the costs or increase the revenues of participants. For this reason, they are presumptively efficient. But they are not invariably efficient, and even efficient ventures may pose competitive threats, or may be organized in alternative ways that will reduce dangers to competition.

The reason for possible inefficiencies is that although profitmaximizing firms decide whether to participate in joint ventures by weighing the costs and benefits of the venture against the costs and benefits of alternative forms of organization or contract, firms are concerned only with private costs and benefits. For example, a firm might decide whether to manufacture its transistors or purchase them from others by comparing marginal costs and benefits. But the same firm might decide whether to participate in a cartel or compete with the cartel by engaging in precisely the same calculus. Although the cartel is socially costly, the firm will participate if it calculates that **[*16]** private benefits exceed

private costs and risks, including the risk of detection and prosecution for antitrust violations.

For a firm to consider costs that are borne only by others is inconsistent with profit-maximization. As a result, the profitmaximizing firm is generally indifferent whether its improved profits come from increased efficiency or increased opportunity to exercise market power or impose burdens on rivals. A well designed antitrust policy changes incentives by increasing the costs or risks attending anticompetitive joint ventures, or by creating similar disincentives to anticompetitive rule making within joint ventures that are otherwise efficient.

B. Performance: Static and Dynamic

Traditional, or "neoclassical" economics looks at joint ventures mainly through a set of static snapshots that can exaggerate the importance of the immediate relationship between price and marginal cost. By contrast, "dynamic" economic analysis attempts to measure the tradeoff between current prices above marginal cost and the incentive to innovate. A temporary period of monopoly prices may create the incentive that firms need to develop new products, processes, or modes of distribution. In the case of the single firm, American patent policy has always understood this relationship, and an important purpose of the Patent Act n42 is to encourage firms to innovate by promising awards in the form of temporary freedom from competition, n43

The dynamic claim made for joint ventures, however, goes much beyond the assertion that single firms who innovate should acquire exclusive patent rights. The claim made for joint ventures is that the promised innovation justifies even the loss of immediate competitive incentives resulting from the structure of the joint venture

itself. For example, the comprehensive production joint venture initiated by all the firms in a market might certainly yield patented products or processes for which the venturers could claim the right to exclude rivals once the promised innovations were developed. But aside from any patents, the venture might also entail an indefinite period in [*17] which coordination of prices or exclusion of rivals is profitable. The strong claim for joint ventures is that the tradeoffs between static inefficiencies (i.e., prices higher than marginal cost) and the promise of future innovation justifies even these structural impairments of competition, n44 Further, the impairment of competition in the joint venture can last indefinitely. Nothing limits it to the Patent Act's seventeen year exclusive grant. If a venture such as BMI, NCAA, or Visa acquires the power to collude or exclude, it may hold that power both immediately and indefinitely, whether or not the promised innovations ever materialize, are shown to have social value, or produce gains large enough to offset any losses from reduced incentives to compete.

In some cases, the tradeoff between innovation gains and competition losses is undoubtedly justified. But in other cases it is not. As long as individual business firms maximize profits without regard to whether the source is increased innovation or merely increased monopoly, antitrust policy must consider at least the possibility that the real private benefits from a venture are coming from collusion or exclusion, not from innovation. Alternatively, although the venture does in fact produce socially beneficial innovation, as a by-product it may also reduce competition in ways that are not essential to the functioning of the venture.

Static analysis focuses on the short run, while dynamic analysis concentrates on long run considerations. But the same thing can be said of anticompetitive practices.

Price-fixing focuses on market power in the short run; exclusion, particularly if it is strategic, focuses on market power over the long run. When one changes from static to dynamic analysis, one must not neglect to apply it to both the competitive and the anticompetitive potential.

Static analysis, which is the traditional method of technical neoclassical economics, looks at price/cost relationships at any given instant -- for example, the relationship between price and marginal cost, or between marginal cost and marginal revenue. If price equals marginal cost, the seller is said to be behaving competitively. If price exceeds marginal cost, the seller [*18] is said to have a certain amount of market power. Under static analysis, consumer welfare is measured by reference to these same relationships. Competitive prices are said to maximize the size of consumers' surplus, and are thus consistent with maximum consumer welfare. Monopoly prices, which occur when marginal revenue deviates from price, usually take some of this consumers' surplus away, and thus are said to be inconsistent with maximum consumer welfare. Strictly speaking, static analysis does not consider where the market is going, or whether what appear to be monopoly prices today are a necessary predicate for even greater consumers' surplus at some future time. The familiar lines in a neoclassical graph of marginal cost, price, and marginal revenue simply fail to provide that kind of information.

By contrast, dynamic analysis looks at firrm behavior or consumer welfare over time. It is more inclined to see the creation and destruction of monopolies as a process, The dynamic approach looks at the lines on the neoclassical graph, emphasizes that they can be shifted, and then asks what kinds of things might cause the shifts and what are the likely results. Under dynamic analysis, the most important shifter is innovation. Further, the motivation for innovation

is economic, or monopoly, profits. At this point, static and dynamic analysis can deviate from one another rather sharply. If the goal of antitrust policy is to maximize consumers' surplus, static analysis virtually always sees monopoly as bad. By contrast, dynamic analysis begins with the premise that the availability of monopoly profits is an essential component of innovation. At least some instances of monopoly profits are simply steps in a process through which consumers' surplus is enlarged.

To take a simple example, suppose that Alcoa is one of many competing steel manufacturers. It develops a process for making aluminum, which it patents, and becomes an aluminum monopolist. Not only does Alcoa sell its aluminum at a substantial monopoly markup above its costs, but its aluminum also takes about 30% of the market formerly occupied by steel. Before Alcoa developed its process, the market sold one hundred units of steel; marginal cost was $1.00 and the price was $1.00. After Alcoa developed its process, the market sells seventy units of steel at a marginal cost and price of $1.00. It also sells thirty units of Alcoa's aluminum, for which Alcoa's marginal costs are $1.10 and the price $1.50. **[*19]**

Rigid static analysis would show a single competitive market before aluminum was invented. It would show a smaller competitive market and a second monopolized market after aluminum was invented. If the two products were lumped together in a single market, it would show average prices exceeding marginal cost, and the creation of some deadweight loss normally associated with monopoly.

Nevertheless, it would be patently silly to conclude that consumers are worse off in the partially "monopolized" market that includes aluminum than they had been in the completely competitive market that did not include it. No

consumer is being forced to purchase aluminum. Rather, some are voluntarily substituting aluminum for steel because they prefer aluminum at prevailing market prices. So consumers' surplus must be just as high under the monopolized steel-aluminum market as it had been under the perfectly competitive steel market. No consumers are worse off: those who had been able to purchase steel for one dollar in the past can still do so; those who prefer aluminum at $1.50 can purchase that instead.

In the above illustration, the development of aluminum is a Pareto improvement as well, or at least a potential Pareto improvement, even though it results in monopoly, n45 This fact is completely inconsistent with the traditional neoclassical view that perfectly competitive markets are Pareto superior -- that is, that once perfect competition has been achieved, no alternative state of market affairs can make one person better off without making at least one other worse off. The problem with neoclassical analysis is that it assumes a given list of products and preferences, and then considers what will maximize satisfactions given that list. Perfect competition is the answer, n46 **[*20]** What the analysis does not consider is that if a new product suddenly appears, buyer preferences may change, and some new equilibrium will be superior to the old one. For this reason dynamic analysis disputes the importance that traditional economic analysis attaches to equilibrium; the more interesting and most common status of markets is change, and the gains from change can dwarf the gains from stability, even when only the stable situation can be characterized as perfectly competitive.

To be sure, the new situation (competitive steel plus monopolized aluminum) is not Pareto optimal, for there are yet further improvements: consumer welfare would be even higher if aluminum were sold at its production cost of $1.10 rather than $1.50. But that is hardly the right comparison,

because it fails to consider why Alcoa developed aluminum in the first place. Suppose the law required that the instant aluminum was marketed it had to be sold at its cost of production. Why would Alcoa bother, given that it is already earning the competitive rate of return in steel? Further, if there were any amount of risk at all -- even a five percent chance that the process would not work out, so the investment in innovation would be lost -then the anticipated returns to developing aluminum would be negative.

In sum, (1) the aluminum monopoly, at least a temporary one, is necessary to create the incentive to innovate, and (2) no one is worse off if the pre-innovation market remains as an available alternative, no matter how high the monopoly price on the innovated product. Suppose, for example, that slide rules were sold for $10.00 in a highly competitive market. The inventor of the first electronic calculator, which is offered as a substitute for slide rules, can make one for $10.00 but sells them at $500.00, an extraordinary monopoly markup. This high degree of monopoly notwithstanding, consumers are not injured because anyone who wishes to purchase a slide rule can continue to do so. Those customers who opted for the calculator did so because that choice made them better off.

This analysis, quite common in the literature on innovation and growth ever since Joseph Schumpeter's day, is simple and intuitively obvious, n47 Schumpeter believed that the neoclassical **[*21]** focus on "equilibrium" seriously underestimated the impact of innovation on economic welfare. For example, the theory of competitive equilibrium assigned the highest welfare standard to perfect competition, a state of affairs where no firm earned any monopoly returns. But Schumpeter believed that this theory neglected to account for the fact that economic profits are the incentive to growth, n48 and more importantly, that a certain amount of protection from competition was

necessary to enable a firm to undergo the risks and costs of expensive innovation, n49

Schumpeter's insights began a debate that has never ended over the relationship between large firm size and innovation, or between monopoly power and the rate of innovation, n50 It is also readily applied to joint venture analysis. We respect joint ventures because they do something other than merely fixing prices or reducing output. They either permit firms to attain economies of scale or scope, which shift costs downward and thus make consumers better off; or else they reduce the costs or individual risks of innovation, broadly defined, and thus permit more innovation to occur than if all of it had to be undertaken by individual firms. In these cases, at least part of the improvement in consumer welfare is dynamic, in the sense that it results not from the elimination of monopoly, but rather from changes in cost or demand, or from the presentation of market alternatives that were not available before. **[*22]**

Schumpeter's conclusion that the gains from innovation can sometimes swamp short-term monopoly losses is relatively uncontroversial today. But this says nothing about degree or frequency, and it is hardly a foregone conclusion that monopoly invariably produces more innovation than competition. Monopoly can just as easily produce sluggishness or complacency, n51 In sum, permitting monopoly as an inducement to innovation, as the patent laws do, is very likely a welfare enhancing policy, provided we can come up with the proper set of rules for identifying the scope and nature of the monopoly we wish to permit. But a broad assumption that any creation of monopoly will naturally result in more innovation seems completely unjustified, n52

The most enthusiastic supporters of joint ventures believe that antitrust has been hostile to them mainly because it has failed to appreciate dynamic efficiency gains, and has exaggerated the effect of static efficiency losses, n53 For example, courts would look at the aluminum story recounted above and see only that aluminum is "monopolized," not that the market as a whole is larger and better for consumers. The remedies that the courts then fashioned effectively took away the rewards to innovating aluminum. Clearly, when a market dominating joint venture comes into existence one must be sensitive not only to its potential to exercise static market power through collusion or exclusion, but also to its ability to produce dynamic efficiency gains.

But the dynamic story has another side that cannot be overlooked. Writing on industrial organization often uses the words "dynamic" and "strategic" to capture two variations of the same phenomenon: that markets shift over time, and that the shifts are driven both by changes in consumer demand and by changes in firm decisions about how and what to produce. The connotations attached to "dynamic" and "strategic" are often different. **[*23]** The word "dynamic" generally looks at the market as a whole, and often emphasizes the more optimistic results of change, such as new innovation and the resulting demand for it. "Strategic," by contrast, generally looks at the extent to which individual firms position themselves or their products in order to maximize their own private returns, even though some alternative position may be best for consumers. For example, firms may select particular technologies, not because they are superior, but simply because they impose higher costs on rivals, n54 Alternatively, a group of firms may exclude a rival's product from the market simply because they fear that what the rival offers will threaten their own market shares, n55 In this way, agreements expressly designed to facilitate innovation

can actually retard it. Any approach to antitrust that wishes to take dynamic concerns about innovation and growth into account must also be sensitive to the possibility of strategic manipulation -- an equally "dynamic" concern, n56

Although joint ventures may have a great capacity to innovate, their members may also profit by retarding innovation, n57 Returning to the steel-aluminum example, suppose that the steel makers were organized into a joint venture that controls the patents for a highly efficient smelting process. Now when Alcoa, one of its more aggressive members, acquires a few patents and begins researching and developing aluminum, a controlling majority of the steel makers pass a rule that any company developing aluminum will be denied access to the smelting **[*24]** technology. Alcoa now has the choice either to leave the venture and try to develop its own smelting process, or else to cease developing aluminum. This venture has not facilitated innovation; it has retarded it.

A short sighted view of this incident is that the steel company's act had no bad economic consequences at all, assuming that the members of this joint venture were pricing their output at competitive levels both before and after the exclusion rule was passed, n58 That is to say, the competitive market for steel continues to exist. But in fact the firms acted anticompetitively: they restrained the development of a new product that threatened to steal their markets shares or deprive them of their competitive returns on investment. Just as dynamic analysis insists that we look at the longer run to see if gains are possible, so too we must look at the longer run for welfare losses. Changes in markets produce both gainers and losers. As a result, we cannot simply revert to static analysis and identify an outcome as competitive or monopolistic by looking at the relation between price and marginal cost. If dynamic analysis is to be used to justify the social improvements accompanying

joint ventures, the same analysis must be used to estimate their social costs.

But why would the steel venturers wish to exclude aluminum, given that they were earning only competitive returns anyway? A quick glance at the fate of the slide rule manufacturers provides the answer. Innovation injures non-innovating rivals of the innovated product even if these rivals were formerly behaving competitively. The innovation may give the innovator lower costs or it may significantly reduce marketwide demand for the older product. It may even put some or even all of the makers of the older product out of business, n59 In sum, **[*26]** when one looks at long run considerations, anticompetitive behavior cannot be limited to present collusion or even the ability to collude.

Strategic exclusion by joint ventures is hardly a rarity. In the last decade and a half three cases have found their way to the Supreme Court, about as many as on any substantive antitrust **[*27]** subject. They have involved both member exclusion and product exclusion, n60 Hydrolevel involved a claim that certain members of the American Society of Mechanical Engineers conspired to withhold approval of the plaintiffs mechanical safety switch, which was a technological improvement over the switch of rivals that orchestrated the disapproval, n61 Allied Tube involved an association containing manufacturers of steel conduit who agreed with each other to exclude plastic conduit, a competitive alternative, from the market, n62 The Insurance decision involved an agreement among dominant insurers to exclude from their venture long-tail insurance coverage that covered events occurring before insurance took effect or losses occurring after the policy expired, n63

In Allied Tube, a group of manufacturers of building materials, which included makers of steel conduit, n64 were members of the National Fire Protection Association ("NFPA"), an organization which developed and updated a model electric code, mainly for use by state and local governments in setting standards for construction. The code was highly influential. Many local governments adopted it virtually verbatim, and many insurance companies refused to insure buildings that did not meet the code's requirements, n65 Then, Indian Head, a relatively small firm, developed an alternative to steel conduit made of polyvinyl chloride. This plastic conduit was cheaper to make and cheaper and easier to install. Further, since it was made of a non-conductor, it was less susceptible to short circuits, n66 When Indian Head attempted to have the plastic conduit approved in the NFPA's model code, the defendant makers of steel conduit "packed" the relevant NFPA meeting with their own agents and **[*28]** employees. Allied alone sent 155 people to the meeting, most of whom had no knowledge about the merits of plastic conduit, and the new conduit was disapproved by a vote of 394 to 390. n67

One important thing to note about the exclusion of plastic conduit -- a point to which we return later -- is that the exclusion was not only inefficient, it was also inconsistent with the interests of the venture as a whole. If the venture as a whole is considered as a single firm wishing to maximize sales and profits of its various products, it would almost always profit from a new product successfully brought to market, notwithstanding that the new product reduced market demand for some older alternatives. For example, Intel profited from designing the 486 computer chip even though one effect of the new chip was to reduce demand for its older 386 or 286 chips. Further, if the venture is considered as a single firm wishing to maximize its influence with consumers of its fire code, such

as local governments and insurers, it does this by approving all safe, economically useful products and by disapproving those that are unsafe.

In sum, a single firm would ordinarily lack the incentive to withhold development of the plastic conduit simply because sales of steel conduit would suffer. The inefficient exclusion occurs because the joint venture is not a single firm: some firms in the venture are dedicated to one technology or process, while other firms are dedicated to alternatives. Some members, such as Indian Head, are better off if plastic conduit is approved. However, other members, such as Allied Tube, are better off if it is excluded.

In the Supreme Court's 1993 Hartford Fire Insurance decision, n68 liability insurers jointly participated in Insurance Services Office ("ISO"), a joint venture heavily involved in the development of insurance forms, classification and assessment of risks, and the like. One of ISO's most important duties is to collect risk and payment data with respect to each of the forms of insurance coverage offered by ISO members. Without adequate statistical data on risk and payout, premiums cannot be computed accurately. Further, the larger the base from which **[*29]** the data are taken, the more accurate the data. For many losses, individual insurers would find it uneconomical to offer the coverage if they had to rely on the risk data supplied by their own policy holders, n69

The defendant insurers, who were sufficiently large and numerous to control ISO, allegedly wished to stop writing "occurrence" policies and write only "claims made" policies. An occurrence policy covers both losses that occur while the insurance is in effect, even though the claim may be made later, and claims that are made while the insurance is in effect, even though the loss may have occurred earlier. As a result, under an occurrence policy lasting one year, the

insurer's exposure can last far longer, particularly for losses from such things as underground pollution caused by leaking gas tanks and the like. In such cases, the interval between the occurrence and the claim can be several years, because the injury may not be discovered until long after it has occurred. By contrast, "claims made" policies cover only those claims that are made while insurance is in effect. The defendant insurers also wished these policies to contain a non-retroactivity clause that denied coverage even for claims made during the insurance period, if the act upon which the claim was made had occurred before the policy took effect, n70

The defendants allegedly instructed ISO to stop gathering and promulgating the risk data necessary to compute premiums for occurrence based policies and for retroactive loss claims. As a result, smaller insurance companies that wished to continue writing the broader forms of coverage were effectively unable to do so, because their risk data were not adequate.

Once again, if the insurance joint venture had been a single firm, it would have profited by offering any form of coverage that produced enough profits to make it a worthwhile investment. If one class of customers wanted the broader coverage and was willing to pay its costs, this single firm would have offered the coverage. The anticompetitive consequences result from the fact that the venture contains two different groups of insurers, one that wishes to offer the broader coverage and one that wishes not to. If the latter group obtains control of the [*30] venture's data collection services, it can force an outcome which may be consistent with its own interests but inconsistent with the interests of the industry as a whole.

In sum, joint ventures sometimes act anticompetitively because the interests of individual members, who are individual profit-maximizing entities, are inconsistent with those of the entire market that the venture represents, but the smaller group manages to control the decision making of the venture, For this reason it is almost never appropriate to treat exclusionary acts by joint ventures as if they were acts by single firms, n71

The Allied Tube and Insurance cases also illustrate that innovation and new product design need not be tied to high technology. Often the innovation is simply a new mode of distribution that consumers prefer, or a new configuration of an old group of goods or services. The market generates a demand for the new product, process or distribution method, but the joint venture excludes or delays it.

III. The Antitrust Legacy Concerning Joint Venture Exclusion

This section briefly examines the most important antitrust decisions dealing with member exclusion or product exclusion by joint ventures. The antitrust concern is easily stated but often difficult to measure. The goal of antitrust should be to make joint ventures perform as competitively as possible consistent with maximum innovation and with preserving the appropriate incentives for entering into the venture in the first place.

In analyzing joint ventures generally, both the Supreme Court and the lower courts have traditionally emphasized shortrun, static analysis, n72 They have only rarely permitted ventures recognized to create substantial market power, and even then have permitted them only when the effect on immediate output was positive, n73 They have never approved a venture conceded to create

substantial and immediate market power [*31] upon the argument that the venture was highly likely to facilitate innovation and greater consumer wealth in the future.

Although one could argue that the Supreme Court is not taking dynamic considerations seriously enough, the refusal to acquiesce in actual, presently measurable market power on the promise of increased but uncertain innovation in the future is hardly irrational. Moreover, analysis of dynamic considerations can lead in both directions, n74 When one considers the impact of changes in demand or supply, the exclusionary acts of a venture can look both more competitive or less competitive than simple static analysis indicates. While a venture may promote innovation, it may also retard it, and one cannot presume one way or the other without close inspection.

A. Trans-Missouri and Terminal Railroad

Elaborate joint ventures are hardly new to courts deciding antitrust cases. Although the 1912 Terminal Railroad decision n75 is sometimes identified as the first important joint venture case, it is not. The very first antitrust case that the Supreme Court decided on the merits involved an ongoing, "network" style joint venture as elaborate as the one in Terminal Railroad. The Trans-Missouri Freight Association was a joint venture of 18 railroads operating in all states and territories west of the Mississippi. n76 The lower court opinion upholding the arrangement explained it very well:

The fact that the business of railway companies is irretrievably interwoven, that they interchange cars and traffic, that they act as agents for each other in the delivery and receipt of freight and in paying and collecting freight charges, and that commodities received for transportation generally pass through the hands of several carriers, renders

it of vital importance to the public that uniform rules and regulations governing railway traffic should be framed by those who have a practical acquaintance with the subject n77

[*32]

In the 1890s, the great majority of American railroads were state chartered corporations, and most of them operated within a single state. Further, even the largest railroads connected to only a small percentage of towns and cities. As a result, any comprehensive national railroad system had to contemplate that freight that entered the system on one carrier would be delivered to its destination by a different carrier, and there might be intermediate carders along the way. n78 Although the Interstate Commerce Commission had already been created, it lacked the authority to regulate rates, and had little authority to coordinate scheduling and routing, n79 The rationalization of this system required the railroads to have agreements with [*33] each other about scheduling, about the size and other specifications of hardware, such as track widths, about transfers of cars or cargo, and about allocating the payment for services. Generally the payment was made by the shipper to the railroad that originated the shipment, or, if sent collect, by the recipient to the railroad that delivered it. That railroad then had to distribute the payment to the other railroads that had participated. Whether this distribution could be accomplished in the 1890s (long before computers or even sophisticated adding machines) without agreements setting rates is probably debatable. Nevertheless, in an opinion that overlooked all of these issues, Justice Peckham writing for the Court condemned the Trans-Missouri Freight Association as nothing more than a price-fixing conspiracy. The result was establishment of a judicial attitude toward joint ventures that focused heavily on short-run concerns, and emphasized the dangers of price fixing, n80

Trans-Missouri was a collusion case that did not address the venture's obligation to admit new members. The Supreme Court's Terminal Railroad decision n81 is the origin of much of our antitrust policy respecting the joint venture's duty to deal with rivals. The decision is often cited and discussed with respect to both single firm duties to deal as well as the duty of a joint venture, n82 The Terminal Railroad Association itself was a single corporation organized under Missouri law. n83 At the time of the litigation, this corporation controlled all railroad lines, railroad bridges and terminal facilities needed by railroads for effective transport into and through St. Louis. n84 The Association **[*34]** permitted all railroads to use its facilities, whether or not they were members, and charged both members and nonmembers the same fees. n85 However, one could become a member of the Association -- that is, a stockholder, or joint owner, of the facilities -- only upon unanimous consent of existing members, n86 As a result, the requested relief is somewhat ambiguous. Why would the government trouble itself to get a decree ensuring equal access if equal access were already being granted? The two possibilities seem to be that (I) although the Association was currently offering equal access to everyone, it had the power to withhold access in the future, and (2) although everyone was free to become a customer of the Association, not everyone was free to become a participant, or owner, in the venture itself.

No one wanted to break up the association, however, since it was conceded by all sides to be efficient. Great economies resulted from the fact that a single channel existed for bringing railroad traffic into and through St. Louis. The Association's control of common facilities obviated the need for expensive and unnecessary duplicate lines and bridges, and it meant that all cargo could be efficiently transferred from one carrier to another. There were also collateral results that the Court did not mention.

For example, grain elevators needed to be strategically located at railroad transfer points so that they could easily load and unload the railroad cars. n87 Duplicate railroad facilities would have entailed duplicate facilities such as grain elevators as well. **[*35]**

So railroads and shippers wishing to enter St. Louis may have needed access to the Association's facilities, but why did they need ownership rights? The Court provided little analysis about the importance of ownership as opposed to access. In order to use the terminal railroad facilities, a railroad needed only to be its customer, not its owner. However, the owners were probably charging monopoly prices to everyone, including themselves, and pocketing the high profits. n88 The Court ordered the Association to charge a price that was reasonable given the costs of the facility, n89 but such a decree would be very hard to administer, even for a regulatory agency, and no federal regulatory agency in 1912 had the power to set initial rates. Alternatively, the Court allowed access to any railroad who wished to join the venture. n90

The Court's decree permitted any "existing or future railroad to joint ownership" upon terms that would place it on an equal footing with the present owners. Second, when the Association was re-organized to permit these ownership changes it "must also provide definitely for the use of the terminal facilities by any other railroad not electing to become a joint owner, upon such just and reasonable terms and regulations as will, in respect of use, character, and cost of service, place every such company upon as nearly an equal plane as may be with respect to expenses and charges as that occupied by the proprietary companies." n91

The Terminal Railroad decision has been cited for the proposition that under the decree a railroad could use the facilities of the association only by showing that it

needed access for its survival, n92 But the Court did not assess such a requirement, and the decree went much further than that. First, the Court required no showing that a railroad needed access to the terminal facilities. As a practical matter, access may have been necessary for a railroad wishing to bring its freight into St. Louis. However, in 1912 the United States was greatly overbuilt with tracks, and railroads that were simply shipping their products [*36] through St. Louis had numerous other alternatives. This is borne out by the fact that the venture was also found guilty of short-haul/long-haul discrimination -- that is, of charging lower rates to traffic going long distances and for which St. Louis was nothing more than a place to get across the Mississippi. n93 Indeed, the Court noted that such traffic could as easily cross the River at Memphis. n94

Further, the access question was completely answered by that portion of the decree giving every railroad the right to use the facilities upon payment of a nondiscriminatory rate that reflected the cost of supplying the service. Although a shipper might be able to show a need for access, it could hardly show a need for ownership. The first portion of the Court's decree, which applied to ownership, was not concerned with access at all, but rather with monopoly profits.

But the Supreme Court wisely saw one important thing: if the exclusionary policy were anticompetitive at all, opening up membership would be a far more tractable solution than simply imposing on the venture a duty to serve all paying customers. If the St. Louis terminal facilities were a monopoly, simply ordering the terminal association to accommodate other railroads as customers would not solve the monopoly problem. Prices would have to be regulated, and this would require the ongoing supervision of a regulatory agency. By contrast, the decision entitling outside railroads to become members effectively worked to

break up the monopoly. To be sure, the venture could charge monopoly entry fees, but these fees would have to be paid only once, and would thus require only a single visit to the court. More importantly, opening access changed the duration of the monopoly. A cartel can keep its monopoly power forever while selling to all customers willing to pay the price. But as soon as a cartel is ordered to accommodate new members the cartel itself begins to fall apart, eroding a little with each new firm that joins. [*37] B. Divergence Between Individual and Collective Goals: the Associated Press Case

The Associated Press case represents a dramatic example of how the divergence between individual and system goals can produce anticompetitive results, n95 Associated Press ("AP") was a nonprofit association of about 1200 newspapers formed for the purpose of exchanging news stories. The venture had been established in 1892 strictly as a cooperative among member newspapers. Its purpose was "the collection and interchange, with greater economy and efficiency, of information and intelligence for publication" of its members, n96 Under this astonishingly successful joint venture, the newspaper members themselves wrote news stories, mainly about events in the towns in which they were located or where their own staffs had special expertise. These stories were then distributed by telegraph or teletype ("wire service") to other member newspapers. The venture also hired its own reporters to contribute stories, and it had contractual arrangements with some foreign news services for the provision of news. n97 Association members were prohibited from selling news to non-members, and the Association itself made no such sales.

Any newspaper that wished could apply to join AP, and most were admitted. However, the Association used a series of rules that made joining more difficult if another newspaper located in the same town as the applicant was

already an AP member. Originally, any AP member newspaper could veto the application of another newspaper in the same city, provided that it also competed in the same time slot (i.e., morning, evening, or Sunday). n98 Later on, apparently fearful of antitrust challenge, AP changed the rule and permitted a vote of fourfifths of the membership to veto the veto. n99 That rule was later changed again, to permit a bare majority to approve the application, nl00 There were also financial contribution rules that discriminated **[*38]** against applicants whose town already contained an AP member, nl01

For the first time since Terminal Railroad, the Associated Press case brought to the Supreme Court a joint venture that no one wished to destroy, but whose membership rules seemed to be anticompetitive. Unfortunately, neither the district court's three judge panel n102 nor the fractured Supreme Court did an adequate job of explaining precisely why it was anticompetitive or what kinds of modifications were necessary to "fix" the venture.

The district court's opinion granted summary judgment n103 to the government in an opinion illustrating the worst aspects of the rule of reason as it had been developed in the Chicago Board of Trade decision, n104 Virtually everything was relevant, including concerns about press freedom and protection of readers' interest in diverse news sources, n105 The Supreme Court's **[*39]** plurality opinion treated AP's bylaws as little more than a naked boycott, and applied a virtual per se rule.

With a few simplifying assumptions, the economics of both the AP joint venture and its exclusion rule are easily understood. First, assume that newspapers compete intensely for readership with other newspapers located in the same town and in the same product niche (morning, evening, or Sunday). But these newspapers do not compete

at all with newspapers located in other towns. This was generally the case before 1945, and it is still substantially so today, with some exceptions, n106 Second, assume that news stories reporting the same event are more or less fungible. As a result, there is great demand for one reporter's coverage of the President's inauguration. But a second reporter's coverage of the same event would be treated as nothing more than a substitute for the first. No newspaper would want to run both.

In this case, great economies of scale inhere in the AP joint venture. For example, when the President is inaugurated the Washington Post, a local AP member, can send its reporter to cover the ceremony. That reporter can then wire the story to the other 1199 members of AP. Assuming that wiring costs are zero, AP has now permitted 1200 newspapers to share the inauguration story for less than one twelve hundredth of the cost of sending a newspaper reporter from each newspaper to cover the story.

The cost is less than one twelve hundredth because the result of the AP joint venture is not merely that the news is shared, but also that it is written by the best placed reporter. In this case, the story is produced by the Washington Post because it is much cheaper for the Post to send its reporter to the inauguration eight blocks away than it is for, say, the Los Angeles Times to send a reporter all the way across the country. Indeed, the cost of the reporter's time may be only half as much as the cost of his or her travel expenses. In that case, AP has permitted 1200 newspapers to share the cost of the inauguration for perhaps 1/2000th of the total cost that would be incurred if each newspaper had to send its own reporter. This news sharing feature is what made the AP so successful, n107 **[*40]**

Suppose that Shreveport currently has no AP newspaper and that the Shreveport Times applies for membership. The existing members can be expected to welcome the application. Up to this time Shreveport news was probably underreported because there was no sharing. If a newspaper in AP wished to report a Shreveport story it would have to send its own reporter. Of course, AP or an AP member could do the story and it would then be shared with other AP members. However, because AP has no presence in Shreveport, neither by its own staff or by a member newspaper, getting Shreveport news is relatively expensive. The addition of a Shreveport member newspaper will benefit all venture members, insofar as they would prefer to have Shreveport news at lower cost.

But now suppose that a second newspaper in Washington -- say, the Washington Tribune -- wished to join the AP venture. The President's Inauguration is already being covered by the Post, and we have assumed that all newspaper stories covering the same event are fungible. Therefore, the Tribune cannot offer the fairly dramatic kind of cost reductions that the Shreveport Times does. To be sure, there would be some cost reductions. First, the Tribune would increase by one the number of AP members sharing stories, and as that number increases, the cost to each member decreases. Further, this decrease applies not only to Washington stories, but to all stories that AP members generate. Second, if the antitrust laws permit, the Washington Post and the Washington Tribune, who share the stories anyway, may be able to work out an arrangement under which they divide the market for reporting stories, so as to avoid duplication. For example, the Post might do only politics, and the Tribune sports and crime. **['41]**

In fact, however, most of these sharing possibilities were lost as a result of another anticompetitive rule: even if AP had two newspapers in the same town, member

newspapers shared their stores with other AP members but not with the local competitor, n108 In sum, the venture as a whole would be better off if a second newspaper from a town joined, although not as much better off as it would be when the first newspaper from a new town joined.

But the one firm that would almost certainly not be better off when the Washington Tribune joined is the Washington Post. Before, the Post was the only Washington newspaper that enjoyed the very substantial cost savings brought about by AP membership. The Tribune, by contrast, had to incur all the costs of writing every story it wanted to publish. The result would be significantly lower costs for the Post than the Tribune. Since we have assumed that newspapers compete only within their own towns of publication, the result could be much larger circulation for the Post than the Tribune, or perhaps simply monopoly profits for the Post's owners.

By contrast, if the Tribune were admitted to the AP venture, then the Tribune would acquire cost savings equivalent to those enjoyed by the Post, and competition would drive prices down to a level reflecting the lower costs. Admission of the Tribune would be good for the venture as a whole -- it would reduce members' costs per story. But the Tribune's admission would be worse for the Post, who would now be a competitor rather than a monopolist in its circulation area.

In sum, then, AP's veto rule benefitted individual members that competed with an applicant. However, the rule injured the venture as a whole, which would still profit by maximizing its overall number of subscribers. If AP had been a giant firm owning all the newspapers in the various towns, and then it had a chance to acquire a second newspaper in one town, it would probably do so.

An interesting and distracting development in the AP story has suggested to some writers that the Supreme Court should never have condemned the veto rule. n109 After the Associated Press decision, and very likely as a consequence, AP came to dominate the national market for newspaper wire services. At **[*42]** the time of the AP litigation the market for newspaper wire services contained three alternative services, AP, United Press ("LIP") and International News Service ("INS"). n110 They appeared to be vigorous competitors, nl 11 Unlike AP, both LIP and INS had originally been established as proprietary systems for single sets of newspapers. E.W. Scripps had established UP as a for-profit business in 1907. Later, William Randolph Hearst established INS to serve the Hearst newspapers, although it began serving other subscribers as well. n112 Although AP had by far the largest market share, all three wire services were viable competitors, n113

The result of the Associated Press decree, which essentially opened membership to everyone, was that newspapers had every incentive to join the largest service which had the most participants and thus could obtain the news from the most different sources. Further, scale economies were such that the more members a service had, the lower the costs per news story. AP, being larger, had more offices and could draw from many more sources, n114 Many newspapers forsook UP and INS and joined AP instead, n115 UP and INS struggled along for many years, and finally merged in 1958, forming United Press International (UPI). n116 The post-merger firm did little better, and has filed for bankruptcy twice, n117

Assuming that the Supreme Court's decision forcing AP to open its membership caused the downturn of UP and INS, it becomes clear that the exclusive membership rule was not in the best interest of AP to begin with. A single firm in AP's **[*43]** position would have liked nothing more

than to become a dominant player in the market while its two rivals languished. In addition, the end of AP exclusivity caused AP to become dominant for precisely the reasons that antitrust wants firms to grow: they can achieve lower costs. The gathering of news for transmission on a wire service is probably a natural monopoly, and in an unrestrained competitive war there is probably room for only one wire service --something that the aftermath of the Associated Press decision seems to bear out. nl 18

The Associated Press decision has been criticized as incorrect because it led to this dominance -- that is, to the virtual monopolization of the wire service market, n119 But this criticism is misplaced if it purports to be based on antitrust principles. It is certainly incorrect if it is based on the premise that joint ventures should be treated as nothing more than single entities. If AP had been a single firm it would undoubtedly have wished to take advantage of every scale economy available to it, even to the point of becoming a monopolist. The AP rules permitting individual members to veto applications from competitor newspapers effectively prevented this from happening.

The effect of the Associated Press decision was to condemn a restraint that prevented the AP venture from taking advantage of the efficiencies that were available to it. Individual AP members were permitted -- contrary to the interest of the venture when considered as an economic actor -to preserve monopolies in their respective towns. The Associated Press decision shows antitrust operating in precisely the fashion that antitrust is supposed to operate.

To be sure, the world might be a better place if there were competing news services from which newspapers might choose, but this is not obvious, and in any event it is not antitrust's purpose to regulate markets but only to see that unrestrained alternatives emerge. The concern for

protecting competing news services is not about economic competition at all, but rather a concern driven by our desire to preserve variety in news gathering **[*44]** and reporting -- driven by First Amendment or press freedom rather than considerations of price and output.

Indeed, even for a "monopoly" AP, monopolization is unlikely as long as its membership structure is competitive. Since AP is an organization controlled by member newspapers, it cannot "monopolize" its market by selling to itself at a monopoly price. The only real threat of monopoly comes from local exclusivity. If Washington has only one AP newspaper, and that newspaper has a significant cost advantage over rivals, then that newspaper will be in a position to charge monopoly prices. By contrast, if Washington has competing newspapers, all of whom are in AP, they will compete away any monopoly profits and consumers will get the advantage of both newspaper competition and a wire service of efficient size.

Can AP itself monopolize the market? Hardly. Its owners are also its customers, the newspapers. AP has precisely as much market power in any market as its member newspapers have. It cannot monopolize by reducing the output of stories and charging its members higher subscription prices, any more than Chrysler's transmission division can monopolize by selling transmissions at monopoly prices to the assembly division. Of course, if an AP member newspaper is already a monopolist in its town, it will be able to charge monopoly prices -- but that is not a function of any monopoly power held by AP. If there were a second newspaper in town, however, monopoly would be diminished if the second newspaper were permitted to join AP as well.

Even the variety of stories is no greater when there are multiple news services. Although the earlier discussion assumed to the contrary, news stories about a certain event are not fungible. There may be room on the market for a dozen or more stories about different aspects of the President's inauguration. But it doesn't take a dozen wire services to generate a dozen stories. If the optimal number of stories about the inauguration were a dozen, they would be generated by a single joint venture, just as they would be by a single firm. By reducing the cost of producing and transmitting these stories, a single wire service venture very likely results in wider dissemination of a greater number of stories than would be the case if there were competing wire services with exclusive lists of subscribers, n120 **[*45]**

C. Aspen Skiing as Joint Venture Exclusion

The Aspen decision seems like an idiosyncratic joint venture case since the venture contained only two members before the challenged exclusion, and one afterwards, n121 The act of exclusion was unilateral at both the venture level and the "member" level. But this fact does not change the basic analysis, and the case offers a rather good illustration of how the interests of a single member of a joint venture can deviate from the interests of the venture as a whole.

Aspen, Colorado, offers some of the best skiing facilities in North America, if not the world, n122 The plaintiff, Highlands, was the smaller firm, operating slopes on one mountain in Aspen. The defendant, Ski Co., controlled three mountains. Since the early 1960s Highlands and Skiing Co. had participated in a joint venture offering an "all-Aspen" ski ticket that entitled its purchaser to use the ski lifts of either firm and to ski down any or all of the four mountains. n123 The principal problem that the venture faced was determining how to allocate revenues, and the partners experimented with various methods. For some

time, they simply recorded the ticket numbers of persons using the ski lifts, and allocated revenues in proportion to the times that a skier used Skiing Co.'s lifts rather than Aspen's. Later, the parties attempted a random sampling of skiers. During this period, Highlands' share of revenues varied from 13.2% to 18.5%. n124 Multi-area tickets such as the "all-Aspen" ticket became very popular, and by 1977 accounted for some 35% of the market.

Beginning in the 1977-1978 season, Skiing Co. began to demand increasingly larger shares of the revenue from sales of "all-Aspen" tickets. That year, it refused to participate in the **[*46]** venture unless Highlands were willing to accept 13.2% as its share of revenues, corresponding to the relatively poorest season that Highlands' had had in the past. After several years of negotiating and sparring over division of revenue, Skiing Co. finally told Highlands it would participate in the venture only if Highlands accepted 12.5% of the revenues, considerably less than its proportion of the traffic for any recent year. n125 It soon became clear that Skiing Co. really did not wish to participate any longer in the venture at all, and was effectively making Highlands an offer that it could not accept, n126 During this entire time, the four-mountain "all Aspen" ticket produced through the venture consistently outsold any multi-mountain ticket covering combinations of Skiing Co.'s own mountains, n127 Once the venture terminated, Skiing Co. marketed its own three-mountain ticket, Highlands' revenues dropped, reaching a low of 11 percent of total Aspen revenues by 1981, just before the antitrust complaint was filed.

The Supreme Court affirmed a jury verdict for the plaintiff, finding essentially that, although a dominant firm has no general duty to deal with a rival, deviation from an established course of conduct can have evidentiary significance that entitles a jury to find that the defendant

was monopolizing. The decision has often been criticized for seeming to push the dominant firm's duty to deal too far, n128 but many lower courts have found various methods for confining its reach, n129

Aspen is a good illustration of the differences between the incentives facing the individual firm and the incentives facing a venture precisely because the surviving "venture" contained only a single firm. The record established without contradiction that skiers consistently preferred a four-mountain ticket to any three, two, or single mountain ticket. Further, every year that **[*47]** the "all-Aspen" ticket was sold its sales exceeded those of tickets offering any smaller combination of mountains. Since the costs to the seller for a four-mountain ticket were no higher than the costs of any lesser ticket, n130 a single firm controlling the entire area would have offered the four-mountain ticket.

So why did Skiing Co. wish to stop the joint venture? Mainly because, although overall market demand was greater when the four-mountain ticket was offered, not all of the revenue from the four-mountain ticket went to Skiing Co. Figure 3 illustrates. Demand curve D is the demand for a fourmountain "all Aspen" ticket. Demand curve D', which is below D, is the demand curve for a three-mountain ticket that Skiing Co. could give alone. We assume marginal costs are constant and equal to zero. n131 **[*48]**

[SEE FIGURE IN ORIGINAL]

Given this set of assumptions, any single firm controlling the four slopes would sell a four-slope ticket. Its output would be Q, price would be P, and profits would equal P-O-Q-X. By contrast, if the firm gave only a three-mountain ticket, price would be P', output would be Q', and profits would equal the smaller rectangle P'-O-Q'-Y.

However, the important difference between the four slope monopolist and the joint venture is that in the case of the venture, the larger firm would not get all the revenues from the four-mountain ticket; it would have to share them with the other firm. If the sharing percentage were large enough, the dominant firm would find it unprofitable to participate in the **[*49]** venture. Suppose, for example, that Highland's share in the revenues from the four-mountain ticket were 20%. In that case, Skiing Co. would refuse to participate in the venture if 80% of the profits represented by P-O-Q-X were smaller than rectangle P'-O-Q'-Y. This is the decision that Skiing Co. apparently made when it decided that it was in its own best interests not to participate, n132

At the same time, however, a strong case can be made that Highlands was free-riding by claiming payment in proportion to actual use. That proportion was far more than it would have obtained in a market in which the venture did not exist. Once again, the reason is that although the cost of supplying a ski ticket does not vary with the number of mountains, demand does. Without the joint venture, Highlands would be able to offer only a single-mountain ticket and Skiing Co. would be able to offer a three-mountain ticket, n133 After the venture terminated, Ski Co's market share rose to about 89% and Highlands' fell to about 11%. The purpose of the venture -and the motive each firm would have had for entering it in the first place -- was to enlarge the sales of both parties, but probably in the same proportion that they would have been without the venture. So Skiing Co. could legitimately insist that Highlands accept a lower percentage of revenues that came closer to reflecting the percentage of revenues that it would receive in the absence of any venture at all. The venture ratcheted Highlands' position up from a one-mountain offering to a fourmountain offering; it increased Skiing Co.'s position only from a three-mountain offering to a four-

mountain offering. The result is that although venture-wide output increased, it increased much more for Highlands than for Ski Co, and may not have increased for Skiing Co. at all.

In sum, if Skiing Co. had been a single firm controlling all four slopes, it would almost certainly have offered the four slope ticket, which cost little or nothing more and generated much stronger consumer demand, n134 In itself, that fact certainly **[*50]** does not serve to make Ski Company's refusal to deal (in this case, unilateral) illegal; however, it does serve to illustrate that joint ventures and the firms within them maximize in different ways.

D. Summary

The preceding discussion has suggested the following points, which will be developed in greater detail later:

First, when we say joint ventures are efficient, we mean that they enlarge current output by either increasing demand or reducing prices, both of which are in consumers' best interests. A single firm generally profits by taking advantage of all the efficiencies available to it, and then raising output to the point that its marginal costs equal its marginal revenues. The joint venture is most efficient when it operates just as a single firm.

Second, as both AP and Aspen illustrate, individual firms within ventures have a more complex set of incentives, and different firms may have different incentives. Collectively, they profit when the venture as a whole profits through increased output, increased demand or lower costs. However, their individual fortunes also depend on their individual share of the market, or their individual share of sales within the venture. When these

interests collide, the individual member may make a decision that is inefficient because it reduces venture-wide output, but is profitable for the individual firm because it increases (or avoids diminution) of that firm's share of sales within the venture itself.

From the venture's perspective, the optimal decision is the one that maximizes the venture's profits, taking advantage of any monopoly power that the venture might have. For each individual venture member, however, there are two independent questions: (1) how big is the venture's output, and (2) how big is the individual member's share of the venture's output. Further, when individual members vote, they vote their individual choices. Thus, for example, individual members are likely to exclude a rival who threatens their own individual profits, notwithstanding that admitting the rival would increase venture-wide output. This serves to distinguish joint ventures from **['51]** firms. It also explains the anticompetitive rule in the Associated Press or VISA cases, under which the joint venture pursued a general policy of admitting all qualified applicants, but specifically excluded certain applicants who competed, n135

Third, the problem of differing incentives is exacerbated by the fact that the interests of the system as a whole must also reflect the interests of those that are being excluded. The latter category includes both those that are being expelled, as in Aspen, n136 or those that are never permitted to enter in the first place, as in Terminal Railroad, n137 Associated Press, n138 or VISA. n139 Since non-members are not entitled to vote on membership decisions, joint venture rule making processes cannot be expected to take into account the level of output that is optimal for the joint venture as a whole, n140

Fourth, if the venture as an organization lacks market power (measured system-wide), then no anticompetitive consequence can flow from individual members' decisions not to maximize the venture's output. But if the venture has market power, then when the venture's output is reduced, the market's output is reduced as well.

Fifth, as a general matter, free rider problems exist because a firm is able to take advantage of investments made by someone else, thus reducing the incentives that others have to make those investments in the first place. As a result, the hallmark of free riding is reduced output, n141 Analysis of free riding is complicated by the fact that different members may benefit from the venture to different degrees. When that happens, the firms that obtain the greater marginal benefit tend to gain **[*52]** market share, while those that obtain a relatively smaller benefit tend to lose market share, n142

But free rider problems do not always exist, and they do not exist merely because they are asserted. If the venture was closed from its inception, forcing late entry could substantially reduce incentives to the formation of similar ventures in the future. By contrast, if the venture is open to latecomers as a general matter, then free rider claims based on entry-time risks cannot be maintained, n143 Although alternative free rider claims are certainly plausible -- for example, a new member may steal the intellectual property of the venture and apply it to other uses -- they need to be established. As a general matter, such claims should be rejected if the impact of the new member's sales would be to increase venture-wide output, n144

IV. Concerted Rule-Making, Joint Venture Exclusion and the Problem of Incentives

A. Introduction: Joint Ventures as Combinations

On its output side, a joint venture often resembles a single firm. It often produces a single product or service and sometimes even acts as seller or decision maker in the market that it supplies, n145 On its input side, however, a joint venture is an association, or combination, of two or more economic actors. These actors may not have the same incentives or motives; they may be competitors but need not be. Individually they often do not have the same incentives as the stated incentives of the joint venture itself.

When examining the legality of a particular joint venture or one of its policies, the antitrust policymaker must initially decide whether the joint venture should be treated as a single **[*53]** entity or as a combination of independent actors. The answer is important because antitrust generally reserves its more hostile treatment for concerted activities. The presumption against them is often stated to be strong, at least when the independent actors are competitors. By contrast, antitrust generally looks on unilateral acts much more circumspectly, condemning them only in cases of clear market power and obvious anticompetitive effects, n146

Antitrust policy has always regarded joint ventures as combinations -- that is, as associations of independent economic actors making joint decisions. As a result, the treatment given to them has generally been harsher than the treatment accorded to single firms acting unilaterally. How much harsher depends on the question being asked and the period of antitrust history in which the answer was given. Although there have been some excesses, n147 the courts generally have been correct. Given the opportunities for collusion, and the differing incentives that motivate joint

venture systems and individual members, it is simply not appropriate to treat ventures as single firms. At the same time, however, courts have often gone too far -- as, for example, when they treat a productive joint venture as nothing more than a cartel, n148 Nevertheless, a joint venture is not a firm and it would be foolish for antitrust to treat them as if they were.

B. Joint Ventures as Economic Actors: Divergent Incentives

Natural persons and business firms are economic decision makers. This means that for purposes of economic analysis they are treated as single actors that maximize their own well-being, **[*54]** and their assessment of well-being is self-reflective. In the case of natural persons, maximization refers to utility; in the case of firms, it refers to profits. For example, the profit-maximization model of the firm generally does not take into account that the firm's managers or other decision makers have individual utility curves. Individually, these people may, among other things, prefer to work less, have larger retirement funds, bigger salaries, more fellow employees doing the same job, or whatever. But we generally trust that the firm's need to maximize its profits overcomes all these potentially conflicting individual preferences. For example, neoclassical price theory regards the firm as a profit-maximizing entity and does not give any special consideration to the conflicting preferences of its managers or other employees, n149

The most important difference between joint ventures and firms is that joint ventures are aggregations of economic actors; they are not economic actors themselves. Further, the structure and nature of joint ventures is such that they can often make decisions in ways that do not maximize the profits of the venture as a whole.

We assume that firms make decisions reasonably calculated to maximize their own profits. If the profit maximizing decision for the individual firm is also profit-maximizing for the venture in which the firm participates, then there is no conflict and we can expect that the firm will execute the profit-maximizing decision. In cases of conflict, however, both the firm and the venture may not be able to maximize profits, and the firm can be expected to choose the course of action that maximizes its own profits rather than those of the venture.

In this respect, the closest analogy to the joint venture is the cartel. A cartel is a group of firms that hope to increase their individual profits by reducing output and raising price to the same level that a single-firm monopolist would charge. But cartels, particularly large ones, are often thought to be inherently unstable because the price and output decision that is profit-maximizing for the cartel as a whole is not the same as the decision that is profit-maximizing for any individual member. Each member individually could earn more by producing **[*55]** more than its cartel allocation and selling at least some of its output at a lower price, n150

The analogy between cartels and joint ventures is imperfect, however, because in a bona fide joint venture (that is, one that is not simply a front for a cartel) decisions must be made about many things other than price and output. For example, someone must decide which fn-ms may join the venture. The entry of a particularly efficient new member might increase the output of the venture as a whole, and in the process reduce its costs substantially; however, the same entrant might threaten to wrest market share in the joint venture product from existing members. This choice creates a conflict between the "venture," regarded as an entity, and at least some of its members.

In this case it is quite possible that (1) the venture as a whole would experience higher per unit profits, higher output, or both, if the new member joined, but (2) every existing member would be worse off. This would happen if the venture as a whole becomes more efficient but all the gains accrue to the new member.

For example, the VISA/Dean Witter case is an antitrust dispute that arose when Dean Witter, the owner of Discover Card, was denied its request to join the VISA joint venture, n151 VISA was a "network" style joint venture of approximately 6000 members with an elected rule-making board, n152 Each member bank issued its own VISA card and set its own customer terms, such as interest rate, grace period, and annual fee. Further, each member bank could decide how many cards it wished to issue, n153

Dean Witter's Discover Card, like VISA cards, are general purpose charge cards. Unlike VISA, however, Discover is a proprietary card issued and managed by a single firm. Had Dean Witter joined the VISA venture, it would have been able **[*56]** to offer a Discover/VISA package, as well as low fees, that would be attractive to many customers. Further, because the cards appeal to different groups of consumers, joint marketing would have enabled Dean Witter to expand its customer base.

In addition, Dean Witter could use parts of the same financial infrastructure to support both cards, thus creating multicard economies of scale or scope. System wide, the likely impact of the venture would be more VISA cardholders and a greater volume of VISA transactions after Dean Witter's entry than before; so the entry would be presumptively efficient, n154 At the same time, however, the VISA/Discover package might threaten the market position of existing VISA card issuers who were not in a position to offer an equivalent package. The existing

members of the venture passed a bylaw forbidding issuers of competing cards to join VISA. n155 Financial institutions that issued MasterCard were also permitted to issue a VISA card, however, as a result of an exception that had been grandparented in. n156 As a result, the vast majority of the institutions issued both a VISA and a MasterCard -- a practice referred to in the industry as "duality." n157

Why would VISA members be willing to accept competing MasterCard members as VISA members, but not competing Discover Card members? Principally because any efficiency gains that resulted from enlarging the VISA base to include MasterCard accrued to everyone who issued both cards, which was virtually everybody in the venture. Further, to the extent the ability to offer a VISA/MasterCard package was attractive **[*57]** to customers and enlarged the venture's output, anyone who issued both cards would realize the gains from this enlarged output. Any bank who wished could issue both cards and thus profit from any efficiencies that VISA/MasterCard duality produced.

By contrast, although Dean Witter's entry into Visa would expand the Visa base as well as lower its costs, net gains would accrue mainly to Dean Witter; existing members would experience mainly a reduced market share. In this case, Dean Witter promised to be an aggressive VISA marketer, with attractive terms for card holders, n158 In addition, Dean Witter would be able to market a proprietary card (Discover) and a network card (VISA) as a package, just as many banks market VISA and MasterCard, both network cards, jointly.

To the extent that the VISA/Discover package was more attractive to consumers, the base of VISA customers would increase. Although the gains to VISA's profits and output as a whole may have been substantial, all of these gains would go, however, to Dean Witter, as only Dean

Witter issued Discover. Further, customers who wished to have a VISA and a Discover in a package would presumably drop their existing VISA card relationship and switch to Dean Witter's package offering.

In sum, then, entry of Dean Witter into the Visa venture was output expanding and presumably efficient, considering the position of the venture as a profit-making entity. Dean Witter's entry would expand not only the credit market as a whole, but also the market for VISA card holders and transactions. However, the gains from this expansion would go to Dean Witter, and its entry threatened the market shares of current Visa members.

One problem is that no one in such a case takes the viewpoint of the Visa venture, because Visa's individual members, **[*58]** rather than Visa, are the relevant economic decision makers. As a result, Visa suffers from the same incentives problem that cartels do: divergence between the interests of the relevant decision makers (individual firms) and of the cartel as a whole.

If a single firm had been facing Visa's choice, it would not have been concerned that part of the gains from the new product would come at the expense of some existing product. When a firm considers whether to add an additional product, it looks at net gains or losses. It generally matters little that the new product will steal sales from the old product if net profits are higher.

For example, suppose that a venture currently has four members each earning profits of ten, and total venture profits are forty. The venture now has an opportunity to admit a new, particularly innovative member, promising that venture profits will rise to fifty-five. However, twenty of these profits will go to the new member while a little less than nine will go to each of the four existing members. A

single firm faced with an analogous choice (in the form of a proposed merger with another firm or the proposed addition of a new product) would have little difficulty in deciding to proceed with the merger or product addition. It has one set of stockholders, and they would prefer profits of fifty-five to profits of forty; they are generally indifferent as to which division or plant is earning them.

But the joint venture is not a single economic actor with respect to this decision. When existing members vote, they will approve the alternative that keeps their own individual profits as high as possible. If the joint venture as a unit lacks market power, the simple failure to maximize is not ordinarily an antitrust concern, n159 The venture might injure itself: its output reduction will reduce its own market share. However, marketwide output will not be reduced and consumers will not be injured.

But if the venture dominates a market or otherwise wields substantial market power, then we cannot be so sanguine. In that case antitrust policy must deal with two different possibilities: that the venture acting as a unit may maximize its own profits at the expense of consumers; or that the venture may act in ways that are anticompetitive and not in the best interest [*59] of the venture as a whole, but that are in the interests of sufficient members to control decision making. With respect to the latter, it is always relevant that the venture is composed of individual participants who maximize their own (not the venture's) profits.

C. Why do Joint Ventures Fail to Maximize?

Joint ventures fail to maximize for two reasons. First, a combination of high transaction costs and self-interested voting creates a divergence of incentives between individual members and the joint venture as a whole. Second, not

everyone whose wealth is affected by the outcome is permitted to participate in the process of member or product selection.

On the first point, each firm in a joint venture makes choices calculated to maximize its own profits. If internal transaction costs were zero, the correlation between individual profit-maximizing choices and the outcome that maximized the profits of the venture as a whole would be perfect, n160 To take Allied Tube n161 as an example, the introduction of plastic conduit is efficient if the net gains that accrue to its manufacturer are greater than the net losses that accrue to the makers of steel conduit. In a world free of transaction costs, Indian Head would be able to make a transfer payment to the makers of steel conduit sufficiently large to induce the latter to drop their opposition to plastic conduit. Just as a single firm would produce both steel and plastic to the extent market of demand, so would the perfectly functioning joint venture.

But in a world of costly transactions this payment would not be likely to occur. Further, a regime requiring such payments would itself act as a significant deterrent to research. If Indian **[*60]** Head knew ex ante that it could market its newly innovated plastic conduit only by sharing the profits with noninnovators, it would innovate much less. In order to mimic firm behavior, the joint venture would have to reduce transaction costs to a negligible level and solve this incentives problem.

As long as transaction costs are high, the profit-maximizing strategy for the makers of steel conduit is to exclude the plastic and protect their own profits. This yields the unfortunate result that the venture becomes opposed to innovation o-substantially more opposed than a single firm facing the same choices would be.

The most obvious problem respecting innovation by venture members, as in Allied Tube, is that the innovator is often in the voting minority, n162 When joint venture members vote their own individual profits, rather than considering venture wide profits, they necessarily consider the fact that the profits from the individually undertaken innovation accrue to the innovator, not to the venture as a whole. As a result, they will vote for outcomes that fail to maximize venture-wide gains, n163

The second important reason that joint ventures fail to maximize is that excluded firms are unable to participate in the decision making process. For example, the entry of Dean **['61]** Witter's Discover Card is calculated to increase the output of the Visa venture as a whole and make it more profitable. The incremental profits do not accrue to existing members. Instead they all go to Dean Witter, the prospective member. Consequently, existing members can be expected to oppose the entry, and of course only existing members are permitted to participate in the membership selection process, n164

In sum, the structure and decision making process of joint ventures is such that one cannot realistically expect that joint ventures will make decisions that maximize the output of the venture as a whole. Ordinarily, a firm does not violate the antitrust laws simply by failing to maximize. However, the joint venture's failure to maximize has its own antitrust significance. First, we are willing to accept some of the anticompetitive risks attending joint ventures only because they promise greater efficiency. Second, agreements among competitors that achieve less than the competitive marketwide output are a classic concern of the antitrust laws. For a single firm to produce less than the optimal amount is one thing; for a group of competitors dominating a market to agree with each other to produce less than the optimal amount is quite another.

D. Firms, Franchises and Joint Ventures

One way to study the incentive structures in joint ventures is to compare them with two alternative types of organizations: **[*62]** firms and franchises. Consider as an example General Motors, which in the real world is a very large firm in which one parent company owns many subsidiaries. Assume that the subsidiaries are Chevrolet, Oldsmobile, Pontiac, and Buick, and that each subsidiary is involved in the design, manufacture and sale of its own models of automobiles. The subsidiaries share considerable know-how and their automobiles have in common many basic design features. Further, they engage in some joint marketing and considerable joint acquisition of inputs. But each firm designs and produces its own distinctive designs, generally sells through its own dealerships, and attempts, to distinguish its own offerings from those of other GM subsidiaries. Because this union of subsidiaries is a single firm, important decisions having to do with the welfare of GM as a whole are made by GM itself through its Board of Directors, CEO and other managers.

Now suppose that the Buick subsidiary develops a unique design feature that makes its cars far more attractive in the eyes of consumers. For some reason, this new feature cannot readily be shared with or copied by the other subsidiaries; thus Buick's popularity increases at the expense of two groups of rivals. First, Buick steals sales from Ford/Lincoln, Chrysler and other automobile manufacturers, and these sales increase GM's total sales. Second, however, Buick's new feature steals sales from Chevrolet, Oldsmobile, and Pontiac. From GM's perspective, this second transfer is nothing more than a shift in sales from one division to another. These transfers may actually harm the managers of Chevrolet, Oldsmobile or Pontiac, whose compensation, chances for promotion, or job security depend on the production of their individual units. But of

course one of the purposes of creating a subsidiary system in the first place is so that intrafirm inter-subsidiary competition provides a stimulus to increased innovation and sales.

Suppose that before this innovation each of the four subsidiaries was selling 100 cars per day, or a total of 400. After the innovation Chevrolet, Oldsmobile and Pontiac each sell 95 cars per day but Buick sells 125, for a total of 410. GM profits by promoting the innovation.

A well designed franchise system would create the same set of incentives as exist within the firm. n165 If GM were a franchise, [*63] GM would be the franchise, selling its intellectual property and perhaps certain design features and marketing strategies. Chevrolet, Buick, Oldsmobile and Pontiac would all be franchisees, each operating as an individual profit-maximizing entity to be sure, but each operating under a contract with its parent company that has many of the attributes of the parentsubsidiary relationship. Indeed, a properly designed and detailed contract could virtually replicate the parent-subsidiary system, except that the contract would substitute for outfight ownership as the source of GM's control of the franchisees, n166

Once again, the franchisor would want a system that permitted each franchisee to innovate as much as possible, even if the consequence of innovating was to transfer some sales from other franchisees. For the franchisor, the relevant question is whether overall sales increase or decrease. For example, suppose that one McDonald's restaurant in a city was able to take advantage of its unique location adjacent a city park to come up with a highly attractive entertainment/food package for children. The package would steal sales from rivals such as Wendy's and Hardees, but it would also steal sales from other McDonald's franchisees in the same city who, lacking the locational

advantage, would be unable to duplicate the offer. The franchisor, if it has the power, would approve the new offering notwithstanding the possible objections of other franchisees, in order for overall sales to increase.

In this respect, joint ventures differ from both firms and franchises. In firms and franchise arrangements important decisions are made by the parent or the franchisor, whose wellbeing is identical with that of the firm or the franchise system as a whole. GM profits when total sales of GM cars increase, even though sales of one particular subsidiary may decline. McDonald's profits when total sales at all McDonald's restaurants are maximized, even though some individual McDonald's restaurants may suffer. The distribution of sales among subsidiaries or individual franchisees may of course be important for other reasons, but as a general proposition the system as a **[*64]** whole is best off when total sales are maximized, without regard to distribution.

In the joint venture, nothing acts as an effective surrogate for the upstream party (the parent, in the case of the large firm; or the franchisor, in the case of the franchise arrangement). In the GM "joint venture" perhaps Chevrolet, Buick, Oldsmobile and Pontiac would each cast a vote on the question whether Buick can deploy its new innovation. If Chevrolet, Oldsmobile and Pontiac are each profit-maximizers, and each predicts that its own sales will decline as a result of the innovation, they will very likely vote negatively, notwithstanding that the venture's overall sales would increase. Further, if the other McDonald's restaurants in town could vote on whether one of them should promote its unique package, the vote, once again, will very likely be "no," notwithstanding that total sales of McDonald restaurants would have gone up had they voted affirmatively, n167

None of this suggests that joint ventures of competitors should be treated with hostility or that they should be discouraged as a general matter. However, it does suggest that joint ventures do not operate the same way that single firms operate. Indeed, they do not even behave as franchises do. As a result, antitrust policy should not treat them as single firms.

E. The Nature of Joint Venture Exclusion

To summarize the preceding argument: first, the individual members of joint ventures often have incentives that diverge from those of the venture as a whole, if we were to consider the venture itself as an economic actor. This fact, in addition to the ordinary concerns about collusion, serves to distinguish joint ventures from single firms and justifies antitrust's closer scrutiny. The absence of any vertically related "control" also [*65] serves to distinguish the joint venture from the franchise arrangement.

Second, although antitrust policy should be hospitable to joint ventures because joint ventures can reduce costs or improve products, thus increasing marketwide output, the incentives problem affecting individual members of the joint venture is such that joint ventures can sometimes reduce output as well. This happens when the venture's decision makers have individual market share or sales goals that conflict with the "system" goal of maximizing venture output.

Third, antitrust is also hospitable toward joint ventures because they can add a dynamic element to competition by innovating new products or processes. However, the very same ventures may be able to restrain dynamic competition. One of the reasons why joint ventures exclude certain firms-ms is to restrain the development of

product alternatives that would benefit consumers and expand the venture as a whole but injure existing members (or at least a decisive subset of them).

Joint ventures can accomplish these anticompetitive results either by excluding potential members (or dismissing existing members) or by excluding certain products. Competitive concerns are roughly similar. Indeed, often the exclusion of members is nothing more than a device for either keeping a particular product variation off the market or limiting its output. In other words, the exclusion or dismissal of particular firms from the joint venture is sometimes a means to exclude a product that these firms produce or persist in offering.

1. Product Exclusion

Product exclusion occurs when a venture disapproves a particular product, or decides not to permit the product to be produced within the venture. Most instances of product exclusion are probably competitive and in the best interests of consumers. For example, joint ventures engaged in product testing or standard setting may disapprove a product because it does not meet certain performance or safety standards, n168 A joint venture engaged [*66] in product testing or approval would probably not be doing its job if it approved every single offering a member proposed.

Product exclusion, however, is anticompetitive when its purpose or effect is to keep a product or process off the market that consumers would prefer, or that is cheaper to produce, but whose introduction would threaten the profits of firms making rival products. Consider the previously given example of Allied Tube. n169 Both the makers of steel conduit and Indian Head, the maker of plastic conduit, are members of the venture, an association that drafts model

electrical codes. The steel conduit makers conspire to exclude plastic conduit from a sizeable portion of the market by having it disapproved for use in new construction in the model code.

The profitability of this strategy does not depend on collusion, oligopoly, or even on jointly held market power by the steel conduit makers. Even if they are behaving competitively, the steel makers stand to gain by excluding or limiting the growth of a new product that is likely to displace or at least steal a sizeable market share from steel conduit. First, the steel conduit makers have made a large investment in their technology and the plant capacity for manufacturing conduit. Plastic conduit threatens to reduce the demand for steel conduit significantly, and this will give the steel conduit makers excess capacity and probably higher costs, n170 Some of the firms will find the production of steel conduit unprofitable and they will either go bankrupt or close down their conduit divisions. In a world of perfectly mobile resources, with production immediately transferable from one market to another, perhaps a firm would be indifferent to loss of output of a competitively priced product. But in a world where fixed-cost investments are specialized and previously committed, loss of sales can entail large business losses in the short run even though the current returns are only competitive, n171 **[*67]**

At the system level, the market power question must be approached differently. There, Indian Head's injury would result only if the venture had some power to exclude or limit growth in the market overall. For example, if the venture promulgated an electric code, but only a tiny percentage of state and local governments paid any attention to it, then Indian Head's injury would not be substantial. Likewise, if ten different organizations produced such codes and governments chose among them depending on which they thought was most realistic, the

Indian Head might not be injured at all. The effect of the exclusion of a superior product from one particular code would simply be that governments would opt for a different code.

In sum, some kind of market power (or the ability to foreclose from the market or to limit a rival's output or expansion) is generally a predicate to anticompetitive exclusion at the system level. However, at the member level, exclusion can occur and reduce consumer welfare even if the members are numerous and behaving competitively vis-a-vis each other.

Concerning the Allied Tube decision, had there been no venture whatsoever, a competitive market would have produced both the steel and the plastic conduit. Indeed, if plastic conduit was as revolutionary as suggested, plastic may eventually have destroyed the market for steel conduit, just as electronic calculators largely destroyed the business of slide rule manufacturers. The impact of the joint venture's anti-plastic decision was to restrain, rather than further, the development of a new product.

The Insurance decision represents a special case of joint provision and product exclusion, n172 Insurance Services Office, Inc. ("ISO"), is a joint venture that serves various needs of the insurance industry, and includes as members approximately 1400 property and casualty insurers. Although ISO performs many functions, two of them are relevant here. First, ISO develops standardized forms for home owners insurance, automobile insurance, and the like. Second, ISO collects data on risk from its numerous members, merges and analyzes the data, and distributes the results back to the members, n173 Both of **[*68]** these functions are valuable to the industry as a whole, benefit consumers, and fully justify the existence of an elaborate joint venture mechanism. The development of

common forms permits customers to compare, in effect, apples with apples when they purchase insurance. Insurance is a market where the product being sold -- risk -- can be contrived in an infinite number of ways and with any possible variation of inclusions, exclusions, exceptions or qualifications. Further, few customers can make realistic assessments of the risk or expected cost of any particular casualty. The result could be a hopeless array of product offerings and unlimited confusion for consumers. Forms development, a principal activity of ISO, is nothing more than a kind of product standardization. It insures customers that the coverage being offered by one firm is identical to that being offered by another firm, or that the differences in coverage are readily identifiable and highlighted for the customer's attention. This system permits consumers to shop price rather than numerous idiosyncratic differences in coverage. In sum, ISO rationalizes and brings into manageable limits the array of product offerings that the insurance industry is capable of putting out.

Collection and analysis of risk data are equally important because insurers' premiums are based on risk. The better the data, the more accurately that risk can be calculated. Since insurers themselves are as risk averse as any business firms, if they are unsure about the level of risk they will calculate a margin of error into their premiums. In sum, insurance rates are probably lower when the extent and quality of risk information is accurate rather than when it is inaccurate; once again, consumers benefit.

The allegations in the Insurance case were as follows, first, ISO was controlled by a relatively small number of very large insurers; second, these insurers no longer wished to insure against certain kinds of losses where the payout potential was very large -- namely, losses caused by groundwater or land pollution resulting from improper disposal of hazardous materials; and third, these insurers

wished to cover certain losses only if they occurred during the time period that insurance was in effect, n174 At the same time, however, this small group of **[*69]** insurers could not effectively eliminate the broader forms of coverage from the market unless numerous small insurers could be forced to agree. If the larger insurers simply agreed with each other to drop this coverage, customers who wished to have it would simply switch insurers. To prevent this from happening the larger insurers did two things. First, they instructed ISO to develop new forms that provided for the reduced coverage. But second, they instructed ISO to stop collecting risk data on the older, broader coverage forms, n175 Lacking complete, accurate and up-to-date actuarial data, the smaller insurers could not price the older, broader forms of coverage competitively.

The allegations in the Insurance case undermine any notion that there was no difference between unilateral and concerted action within the venture. It would almost never be anticompetitive for a single-firm monopolist to refrain from offering a particular product; but it can become so for the joint venture that restricts output by decreasing the quality/variety of its offerings -- particularly when membership in the venture gives firms a significant advantage over non-members.

Likewise, the dominant insurers were using the joint venture in a way that served their own ends, but probably not those of the insurance industry as a whole, and certainly not those of consumers. Suppose that insurance was sold by a very large monopolist which had two classes of customers. One class was willing to pay for the broader insurance coverage while the other was not. The monopolist would very likely offer both alternatives. It would almost certainly charge a higher premium for the broader coverage. It might engage in price discrimination -- that is, it might charge a premium for broader coverage that was higher in

proportion to cost than the premium for the lesser coverage. The monopolist would probably not drop the higher form of coverage unless the incremental cost of supplying it was greater than the incremental revenues it produced.

The ISO joint venture, however, differed in that the interest of individual insurers was not precisely the same as that of the insurance industry as a whole. Each member had its own expertise and its own investment in the development of its product. **[*70]** Each member competed with other members for the sale of insurance. Depending on size, information, and manager personality, each may have been willing to assume different levels of risk. Importantly, both the purely competitive market (that is, without any joint venture at all) and the monopolized market would probably have produced the sale of both classes of insurance. But the joint venture market did not because one set of insurers were able to control the venture for their own benefit rather than for those of the industry as a whole.

2. Member Exclusion

Member exclusion, as in the Terminal Railroad, n176 Associated Press, n177 or VISA n178 cases, occurs when the existing membership of a venture votes to exclude a new applicant, or perhaps when it kicks out someone who was already a member, n179 The motives for member exclusion are as manifold as those for product exclusion. First, member exclusion may simply be a way of disciplining firms that have been found to be producing substandard products or engaging in unethical business practices. Second, member exclusion may be a device for controlling free riding. In closed membership joint ventures, forcing entry by latecomers would encourage everyone to refrain from investing in the venture during its early, high risk period because everyone would have a right to join later when the risks have been overcome, and thus avoid

investment in a venture that might fail. Third, member exclusion may be a way of facilitating collusion or collusion-like behavior among members of the existing ventures. If the venture gives existing members access to lower costs or some essential input, they can effectively impose higher costs on rivals by keeping them out. This protects the profits of existing members. Even if the new applicant would likely agree to participate, monopoly profits to individual members would decline as the number of members increased, n180 ['71] If the new member threatened to undercut existing prices, member profits would be reduced with or without a cartel. Fourth, member exclusion is often simply a way of achieving product exclusion. In the VISA case, for example, the effect of the exclusion was to prevent the introduction of Dean Witter's VISA/Discover Card package, and existing Visa members from issuing proprietary cards of their own -- but this product exclusion was accomplished simply by excluding Dean Witter from the Visa joint venture altogether, nl 81

When challenged as anticompetitive, the varied nature of member exclusion entails different mechanisms for assessing power. For example, if the excluded plaintiff alleges that the exclusion was designed to facilitate collusion by the individual members of the venture, then it must be shown that the individual members have some realistic capacity to collude. By contrast, if member exclusion is nothing more than disguised product exclusion, then ability to collude at the member level is not important, n182

3. The Extent of Exclusion

In private plaintiff joint venture exclusion cases the plaintiff is nearly always inside the relevant market. If it were not, it would probably lack standing to sue. n183 As a result, "exclusion" refers to exclusion from the venture, but not necessarily to exclusion from the market altogether. The

impact of the decision to exclude may be to drive the plaintiff out of the market altogether, but anticompetitive results hardly require that. Both product exclusion and member exclusion can be anticompetitive even if the excluded firm continues to sell its product. Anticompetitive exclusion is profitable if the venturers succeed simply in limiting the growth of the threatening product or the [*72] aggressive firm applying for membership. For example, in the VISA case the Tenth Circuit apparently thought that since the plaintiff already issued a general purpose charge card, it could not be anticompetitive for the defendant to exclude the plaintiff from its venture, n184 To be sure, the venturers might profit even more if they could shut down Discover altogether, but any rule that made it more difficult for the plaintiff to take away their individual customers would protect their own market shares while harming consumers. Likewise, in the case of product exclusion, it might have been even more profitable for Allied Tube to destroy the market for plastic conduit completely, n185 The profit to the individual venturers comes from protection of their market share. But a second best outcome was one that simply cut the plaintiffs plastic conduit out of certain parts of the market.

V. Significance, Nature and Measurement of Market Power

A. Supreme Court Power Requirements in Joint Venture Cases

Market power must be assessed in all antitrust cases that are decided under the rule of reason. Measuring market power is a highly inexact and expensive science, however, n186 Further, not all market power queries are equally detailed. Sometimes a cursory review of the facts is all that is necessary to establish that the defendants lack any market power at all; occasionally such quick looks even establish

substantial market power. But in the middle range market power inquiries can quickly become elaborate and expensive. **[*73]**

The extent of the market power query varies both with the offense and the nature of the alleged offender. For example, the presumption in favor of a single business firm's unilateral actions is strong, and most unilateral acts challenged by competitors are efficient. As a result, the law of monopolization requires a fairly thorough inquiry into market structure and the ability of the defendant to exercise market power, n187 Indeed, even within the law of monopolization the extensiveness of the market power query varies. For example, predatory pricing is a rational strategy only for a firm that has a reasonable expectation of a very prolonged period of monopoly pricing once the predation succeeds. As a result, the inquiry into entry barriers and, height and duration of the monopoly price increase is much more elaborate in predatory pricing queries than it is in monopolization claims generally, n188

In contrast to unilateral actions, joint ventures and other joint conduct provide greater opportunities for anticompetitive behavior. Unlike predation, which may be an expensive investment taking many years, joint ventures can be formed as quickly as cartels can, and they can be quickly abandoned if they do not work out as planned. The opportunity to earn monopoly profits for just a few months or a year may be a sufficient motive to form a joint venture facilitating collusion. In general, the more cheaply and quickly market power can be created, the less that is needed for profitability. For example, if the costs (including risk of capture) of forming a cartel are zero, then the cartel is profitable even if it makes only one sale at a price above the competitive level.

In this respect, a joint venture differs somewhat from a cartel. The costs of engaging in any joint activity must include the cost of investments that will be lost if the joint activity fails. For cartels, this loss may be extremely small, disregarding the risks of capture and prosecution. For example, the cartel members may do no more than meet in a room and agree to reduce output and raise price. In a joint venture, by contrast, firms may make more substantial investments in the venture. These **[*74]** investments are less than they would be for a single firm, but they can be significant nonetheless. For example, the firms may reconfigure a product, build joint research or production facilities, or engage in joint promotion.

For a collusion-facilitating joint venture to be profitable, the gains from collusion and any efficiencies that the joint venture produces must be large enough to compensate for these investments. Often, this means that a collusion-facilitating efficient joint venture is more likely to be formed than a collusion-facilitating inefficient venture or a venture that does not facilitate collusion. For example, if the venture requires a $100 investment but produces only $70 in cost savings, firms would not find it attractive unless it produced an additional $30 in gains from collusion. But the same venture would be attractive if it produced $100 in cost savings, and from that point any additional gains from collusion would be profitable provided they covered their incremental costs. Since the venture often "sets the stage," so to speak, for collusion, the incremental cost of price fixing, market division, or equivalent collusive activity is often very small. If the costs of forming a joint venture are just equal to efficiency gains, then collusion will be profitable if any incremental gains are available.

For the joint venture the question of the relevant cost and degree of incentives is not the cost of the venture itself, which could be substantial, but rather the incremental cost

of the venture members' engaging in collusion. Joint ventures create opportunities for the short-term, inexpensive exercise of market power that make them more closely akin to cartels than to single firms. Indeed, the existence of the venture may reduce the costs of collusion by giving members ample opportunity to communicate, standardize products or sales terms, or do other things that make collusion less costly. As a result, the market power inquiry in joint activity cases need not be as elaborate as in monopolization cases.

Supreme Court decisions have generally recognized this. In Indiana Dentists, for example, the Supreme Court purported to apply the rule of reason because the defendants were members of a learned profession, and because "the per se approach has generally been limited to cases in which firms with market power boycott suppliers or customers in order to discourage them from doing business with a competitor." n189 However, the **[*75]** Court was sufficiently suspicious about the defendants' horizontal agreement to withhold x-ray data from an insurer that it truncated the market power inquiry to almost nothing at all. The Court reasoned that an agreement among dentists to withhold from their customers a service that the customers want (forwarding x-rays to insurers so that they can verify claims) was identical in effect to a price-fixing conspiracy, n190 Since price-fixing conspiracies are illegal without any market power inquiry, this "rule of reason" inquiry into power need go no further, n191

In contrast, the market power inquiry in NCAA n192 turned out to be more detailed, although not nearly as elaborate as it would have been in a monopolization case. The NCAA rule at issue limited the number of times each participating college could have its football games televised. First, the court found that this was a "naked restriction on price or output," even though it was in the context of a joint

venture, n193 Such a restraint "requires some competitive justification even in the absence of a detailed market analysis." n194 However, then the Court noted with approval the district court's determination that there was a distinct relevant market for college football broadcasts, n195 since advertisers were willing to pay a premium price to reach the audiences that watch college football games.

As NCAA illustrates, the process of rule making within the joint venture set the stage for collusion and even disguised it. We would be immediately more suspicious about an agreement between, say, the NFL, whose members play professional football, and the NCAA, whose members play amateur collegiate **[*76]** football, to reduce the number of televised games. Assuming no other integration of production, that agreement would be a naked cartel. But once the output reduction agreement is placed within the joint venture itself, as in NCAA, its status becomes more ambiguous. The incremental gains from potential collusion are just as present as before, but the risks and other costs involved have declined. Indeed, at the time the output restriction rule was formulated, those involved apparently thought it was legal. The rule itself was explicit in the NCAA agreement and publicly known to anyone who wished to inquire.

In sum, the scope of the market power inquiry must dwell on the potential for incremental gains from collusion. If the venture created no economies whatsoever but promised only gains from collusion, then high formation costs would make its formation less likely. But if the venture produces economies sufficient to justify the costs of its formation and the incremental costs of colluding are small, then small incremental gains would be sufficient to produce collusion as well.

In Northwest Wholesale Stationers n196 the Supreme Court held that the rule of reason governed a concerted exclusion claim arising out of a joint buying venture's unexplained expulsion of the plaintiff. Notwithstanding the venture's lack of explanation for the expulsion or its failure to give the plaintiff notice and an opportunity to be heard, the court declined to place this concerted refusal in the per se class. Rather, it concluded that per se treatment should be reserved for "joint efforts by a firm or firms to disadvantage competitors by 'either directly denying or persuading or coercing suppliers or customers to deny relationships the competitors need in the competitive struggle.'" n197 Further, what was common to cases condemning these practices is that they "were generally not justified by plausible arguments that they were intended to enhance overall efficiency and make markets more competitive." n198 The Court then noted that wholesale purchasing cooperatives such as the defendant were not "characteristically likely to result in [*77] predominantly anticompetitive effects." Rather, they were likely to be efficient, n199 Of course, the plaintiff was not objecting to the venture as a whole, but rather to the decision to exclude him. However, the Court appeared to say that once the venture as a whole seemed presumptively efficient, an ambiguous exclusion would not be automatically placed into the per se class. Rather, illegality would require some kind of showing of "market power or exclusive access to an element essential to effective competition .... " n200 Since the plaintiff had proceeded entirely on a per se theory and had made no allegations of power, dismissal was warranted.

This conclusion, although correct, said nothing about the extent of any query into power. To be sure, a buying cooperative able to reduce member costs is presumptively efficient, and in a broad range of exclusion cases this should entitle the venture to rule of reason treatment. But the

venture might be able to earn even more by fixing resale prices, and the plaintiff may have been a price-cutting cartel cheater. Certainly, an effective way for a cartel to control a cheater is by cutting off its low cost source of supply.

Northwest Stationers certainly should not be read for the proposition that every challenge to a naked restraint, or even every challenge to a concerted refusal to deal, requires a market power inquiry, n201 Rather, in cases of ambiguity about whether the per se rule or the rule of reason should apply, quick looks at a joint venture's market power can guide the inquiry. If the exercise of market power seems impossible, then in ambiguous cases doubts should be resolved in favor of rule of reason analysis and probable dismissal of the complaint. Further, explicit price increasing or output reducing agreements are dealt with more harshly than concerted refusals to deal -perhaps because the latter are viewed mainly as ambiguous facilitators of the former. Thus, Trial Lawyers n202 was not a **[*78]** very ambiguous case because the boycott challenged there was a simple concerted request for higher pay. No claim was even raised that the Superior Court Trial Lawyers Association in any way integrated the activities of the individual attorneys who represented indigent criminal defendants.

If the joint venture integrates production or distribution, then agreements to restrict output or raise prices are still illegal per se unless the defendants can show that the challenged agreement is essential to the functioning of the venture. In the latter case, a rule of reason inquiry is necessary, and the plaintiff will have to show market power. If the challenged restraint is a concerted refusal to deal, the rule of reason will ordinarily be applied unless it is fairly obvious that the concerted refusal is nothing more than a collusion facilitator. As the Supreme Court noted in NCAA, even an elaborate joint venture can incorporate a "naked" restraint, n203 This means that a restraint does not qualify

for elaborate market power analysis simply because it is printed in a joint venture agreement, n204

Thus in most cases involving exclusion from joint ventures that are conceded to be efficient, the rule of reason applies and some showing of power is essential. The one exception occurs when the concerted refusal is itself "naked" -- that is, not even arguably required for the joint venture to achieve its potential. For example, if a joint venture engaged in fixing prices and expelled any member who sold for less, an elaborate market power inquiry hardly seems necessary. n205

Finally, although market power is required, it is not sufficient for a finding of illegality. The Broadcast Music decision illustrates that even substantial market power does not entail illegality. In that case the Supreme Court found a blanket licensing arrangement covering performance rights to be legal, even though it literally involved price-fixing. The clear effect of the agreement was to enlarge rather than limit output, n206 Under **[*79]** the arrangement, owners of performance rights to recordings issued non-exclusive licenses to the defendant, who in turn sold blanket licenses to various licensees such as television and radio stations at prices that varied with the licensee's advertising revenues. Since the blanket license covered all artists, all essentially had to agree to a given royalty rate for each performance of their works. Although the Supreme Court did not discuss power, power can be inferred readily from the venture's market share, as well as the fact that it was able to price discriminate by charging rates in proportion to the buyer's revenues, n207

As Broadcast Music illustrates, ventures that reduce costs substantially can also create substantial market power, particularly if they occupy large portions of a properly defined relevant market. Market power is the ability to

maximize one's profits at a price higher than cost. One can create it either by increasing the price or reducing the cost. Nevertheless, our fears in the Broadcast Music case are alleviated by two facts: any performance right holder who wished was entitled to participate in the venture and the venture itself was non-exclusive. In other words, any participant was free to make as many sales outside of the arrangement as it pleased. As long as the venture admitted everyone who wished to join, and as long as each member was permitted to make unlimited non-venture sales, the nonventure market would always act as a check on the market power of the venture. It could never charge more than the price that had prevailed before the venture came into existence.

B. Nature of the Power Inquiry: Power Over Price or Power to Exclude

Economically, market power is a firm's ability to profit by raising price above marginal cost. The Lerner Index expresses this conception as the degree of difference between a firm's marginal cost and its current, or profit-maximizing, price, n208 **['80]**

But this measure ignores essential questions concerning the time period over which market power is exercised. For example, it avoids inquiry into changes in demand or product design, and the impact that these changes may have on a firm's market position. Further, the economic definition of market power is so tied to the short run that it says little about the firm's power to exclude rivals over time. This question is especially relevant when the practice being challenged is express joint venture exclusion.

1. The Importance of Time in Power Analysis of Joint Ventures

Measures of market power are quite meaningless unless some estimate of duration can be attached to them. n209 The firm capable of operating for a day at the monopoly price before its sales are completely stolen by competitors has market power on day one but not on day two. For example, the 1992 Horizontal Merger Guidelines find market power in the ability of firms to increase price "for the foreseeable future," n210 without losing sales to firms that are already inside the market within one year, n211 or without losing sales to new entrants from outside the market within two years, n212 These are policy judgments, not the results of pure theory. Some tradeoff must be made between the certain but generally unmeasurable efficiency gains that can be had from mergers, and the equally certain but unmeasurable losses that can accrue from increased market power. In the case of mergers, time periods on the order of one to two years seem sufficient. For monopolization we might require more; for cartels less.

Although the durability question is important to antitrust, judicial decisions do not often pose the question in these terms. Rather, the durability requirement becomes more or less important **['81]** depending on the nature of the offense. Consider two examples at the opposite extreme: predatory pricing and naked collusion.

The law of predatory pricing requires a particularly strong showing of the durability of market power. We express this showing through the label "recoupment:" the plaintiff in a predatory pricing case must show that after a period of cutting prices below costs the predator will be able to enjoy a period of monopoly prices in which prices are sufficiently high and the predator is sufficiently protected

from new entry or output expansion by rivals that the predation scheme is profitable, including the time value of the monies spent on the predation itself, n213 This is a particularly strong showing of durability of future market power -- indeed, it is so strong one might doubt that the showing can ever be made. n214 In cases alleging naked price fixing, by contrast, no showing of market power is necessary, and we simply presume that prices will rise from the fact that the defendants apparently think they will rise.

The different treatment is justified by the various ways in which the market power is created. Predatory pricing is an extraordinarily expensive and risky way to create market power and the conduct itself is highly ambiguous -- any price-cost test for predation is likely to generate many false positives. Given the ambiguity of the conduct and the extraordinary expenses that make it an unpromising strategy for nearly all firms, antitrust tribunals use an extremely strong market power requirement to distinguish winning claims from losing ones. n215

Price fixing is an entirely different matter. As a general proposition the investment in it need not be large. Three firm **[*82]** managers can meet over dinner or agree on prices over the telephone, with the increases to become effective the following day. Given this extremely low investment, collusion can be profitable ev6n if the market power thus created is not particularly durable. For example, if entry takes as little as six months, a cartel can earn six months of monopoly profits. Once entry occurs, the cartel members will let the price drop back to the competitive level. At that point they might invite the new entrants into the cartel and start over. Such markets may be characterized by repeated attempts at collusion, repeated "failures," and subsequent attempts. However, what is going on is not "failures" at all, but simply a series of cartels, each of which individually is of relatively short duration but nevertheless

profitable. "Failure" occurs only if the cartel falls apart before it recovers its investment, or if the participants are caught and imprisoned, fined, or assessed large treble damages awards.

Joint ventures occupy a position between predatory pricing and naked collusion. Often, however, the collusion analogy is the most apt: joint ventures can provide opportunities for collusion, and collusion within a joint venture is not necessarily any more costly than collusion outside of one. On the contrary, the existence of a joint venture and the opportunities for communication that it provides can greatly reduce the costs of organizing a cartel and agreeing about the price, n216

2. Dynamic Analysis of Power

If the venture as a whole wield's market power an exclusion decision can be anticompetitive, even though individual members of the venture are not readily able to collude.

As noted earlier, joint ventures often appear to be socially beneficial only when efficiencies are looked at in a dynamic rather than a static context, n217 The new product or process created by a venture may produce consumer benefits that far **[*83]** outweigh any short run ability that the venture might have to set prices above its marginal costs.

What is not so often appreciated is that the very same dynamic considerations that make ventures efficient can also serve to make them anticompetitive. This impairment creates a deadweight loss, or social cost, similar to the deadweight loss associated with market power -- indeed, it is captured by the second half of the Supreme Court's often cited concept that market power is the power to raise prices or to exclude competition, n218

Importantly, when market power judgments take dynamic considerations into account, power or something resembling it can be found even though (1) the firms involved have no realistic ability to fix prices and (2) their prices in fact are continuously "competitive" if one looks at short-run measures such as the relationship between price and marginal cost.

Consider once again the Allied Tube case. n219 Assume that a group of manufacturers of steel conduit lacks any realistic ability to fix prices. They are currently earning returns at or slightly above the competitive level. They have a substantial investment in their production facilities and, more generally, in their commitment to production of things made out of steel. Now a new firm comes along and offers plastic conduit. For simplicity, assume that customers are indifferent as between steel and plastic conduit but plastic costs less to produce.

If the plastic conduit maker charged a price equal to its costs, the steel conduit makers would make no sales whatsoever. Indeed, the plastic conduit maker might be able to charge more than the competitive price and still capture all sales. Depending on its own costs and those of rivals, it might also maximize profits at a higher price that permitted the steel conduit makers to make at least some sales, n220 **[*85]**

For the steel conduit manufacturers, then, the cost of accommodating plastic is either a total loss of sales or else a dramatic reduction in output. If the steel makers are behaving competitively, the result will be loss of investment and perhaps bankruptcy for marginal firms. If they are behaving oligopolistically, the result will be loss of some or all oligopoly profits, n221

Suppose the steel conduit makers succeed in keeping plastic conduit off of the market. This preserves their own output, but has "deadweight" loss effects on consumers that mimic the deadweight losses of collusion generally, n222 However, these losses must be viewed in a more dynamic context. Literally, the market for steel conduit was competitive before steel conduit was faced with the rival plastic conduit, and it continues to be competitive after the plastic is excluded. As a result, there is no "deadweight loss" at all in the traditional monopoly sense.

In sum, then, when one considers the market in movement, firms have incentives to exclude that (a) do not depend on their short-run, or present, ability to set prices at monopoly levels, and that (b) generate Social costs, or deadweight losses analogous to those caused by traditional monopoly or collusion, n223 **[*87]** However, the market may appear to be competitive, with prices equal to marginal cost, both before and after the exclusion occurs.

This does not mean, however, that traditional concerns about market power are irrelevant, for two important reasons. First, the presence of market power increases the incentives to exclude. That is to say, if the steel conduit makers in the above **[*88]** illustration were colluding, the entry of plastic could cost the steel conduit makers even more than if they had been behaving competitively.

But secondly, even though the firms do not have to have the power to raise prices above marginal cost, they may have the power to "exclude." This power is best measured, not by formulations such as the Lerner Index that focus on relationships between cost and profit-maximizing price, but rather by traditional antitrust formulations such as market share, or by determination of access to some unique or essential input.

The Lerner Index measures only the result of market power, not its source. Further, the Lerner Index is itself "static," in that it does not consider the impact on consumers of changes in relative cost or demand. By contrast, more traditional antitrust formulations identifying market power as the power to exclude look to the source of market power. Further, the exclusion formulation is able to take market change into account. For example, DuPont's patent in Cellophane gave DuPont the right to prevent others from manufacturing and selling a certain product. If that product also defined a relevant market, then it may also have given DuPont the power to charge a monopoly price, n224 Although the Court was perhaps imprecise when it defined market power in Du Pont as "the power to control prices or exclude competition," n225 it was correct to conclude that discretion over price does not tell the entire story insofar as antitrust policy is concerned.

At the same time, however, some kind of market power is essential. If the venture has neither the power to control prices nor the power to exclude, then harmful consumer consequences are more difficult to identify. In the conduit case, the relevant power inquiry concerns, not the ability of the steel conduit makers to set a price above the competitive level, but their ability to keep plastic conduit off the market.

The antitrust market power inquiry must carefully identify the relevant market in which the venture operates and then assess the market share of the overall venture. By contrast, the internal structure of the venture may not be all that important, depending on the nature of the antitrust challenge. For example, consider the insurers who try to exclude "long-tail" coverage n226 [*89] by refusing to supply statistical data. n227 If these insurers collectively dominate the market in such a fashion that collection of such data becomes unprofitable, they have succeeded. But if the non-

conspiring insurers are sufficiently numerous or large to supply the data for themselves, then the larger firms will fail and a market for the long-tail coverage will continue to exist. So consideration of market dominance at the system level is important. At the member level, however, it would not matter whether the insurance market was conducive to price fixing, or whether the insurance joint venture had five members or 100. The consumer harm from the venture's decision comes not from collusion, but from the exclusion of a product that consumers would have preferred had it been available. n228

C. Market Power Inquiry at System or Member Level?

A joint venture with 1000 members may dominate a relevant market while individual members have infinitesimally small market shares. The market may look extremely concentrated or extremely unconcentrated depending on which level one examines. Which is correct?

The answer depends entirely on the question being asked. When the challenged practice is thought to facilitate collusion or collusion-like performance but individual members retain nearly all their ability to compete, market concentration at the member level remains significant. For example, suppose 6000 plumbers in the City of Chicago form a co-operative to purchase parts at the lowest possible price and provide seminars introducing [*90] plumbers to the latest technology. Any challenge based on the theory that the venture is raising the price or reducing the output of plumbing services must evaluate the plausibility of 6000 plumbers' fixing prices simply by using a purchasing and educational venture as a facilitator. In this case, market structure at the member level would probably be decisive. By contrast, as the previous discussion illustrated, if system-level power exists then an exclusion decision can be both

profitable to existing members and harmful to consumers even though the existing members are forced to set price and output at the competitive level.

Suppose that the plumbers' cooperative (1) passed a formal rule forbidding any plumber from working more than 40 hours per week and (2) threatened expulsion of anyone who violated the rule. Setting aside for the moment the question of per se illegality for an output restriction agreement, in this case the market dominance of the venture as a whole acquires much greater significance, and the diffusion at the member level is relatively less important.

The key to the difference is the ability of the venture to enforce its position against "cheaters." In this case, one cheats by working extra hours. Assuming plumbers keep an eye on one another, someone who persistently works extra hours is likely to be caught, n229 Moreover, the threat of expulsion from the joint venture is both credible and costly. As a result, the fact that the venture contains 6000 plumbers is far less important than it was in the first case. Assuming the venture can effectively catch and discipline those who cheat by working extra hours, this output restriction agreement may be effective notwithstanding the large number of members.

"Cheating" in a joint venture can occur in two different ways. First, the cheater may cut price or produce more than the venture permits. Second, the cheater may wish to offer a product innovation or variation that the venture seeks to exclude. In response to the first, a cartel of 10,000 members can function quite well if it enacts its price-fixing agreements as binding resolutions, and then obtains the power of the state in enforcing them. For this reason judicial intervention into such things as bar-enforced minimum schedules for legal fees is appropriate, n230 **['91]** In other cases the venture may itself take the price-setting

function away from individual members. For example, under the blanket licensing arrangement in Broadcast Music, individual authors had no say in determining either the price of the license or their own participation in the royalties, n231 Price was set by the venture. In that case it did not really matter whether the venture contained 100 members or 100,000. Of course, if secret price-cutting is possible, then a venture with many members may have a more difficult time policing a cartel than a venture with few members; that is entirely a function of the nature of transactions within the market.

As to the second kind of cheating, product standardization agreements are generally easier to enforce than price fixing agreements, for several reasons. First, the redesign of a product is ordinarily a much more visible act than the negotiation of a price. Whether the steel conduit venture has ten members or 10,000, it would be impossible for one member to develop and market plastic conduit without detection. By contrast, if the venturers had agreed to charge $1 per foot for their product, it might be relatively easy for one member to negotiate a large, secret transaction at a lower price, n232 Second, for many ventures product design is a common enterprise, while price setting is individual. Indeed, the whole purpose of the venture may have been to develop a common product, or a common set of product specifications.

Both product and member exclusion can be accomplished through formal rules whose violations are readily detectable, and where enforcement is easy. To elaborate on an earlier example, suppose that the makers of electrical components have organized the Electrical Components Manufacturers' Association ("ECMA") to promote their industry. Currently the ECMA has **[*92]** 650 members, thirty-five of which manufacture steel conduit. No ECMA member makes plastic conduit. Roughly 80% of

the dollar value of electrical components in the United States is produced by ECMA members. One of the things the ECMA does is prepare model specifications for buildings, and these specifications are widely used by contractors or purchasers soliciting competitive bids for new structures. The members of the ECMA avoid all discussions of price or output. The ECMA now passes two rules. The first rule permits member firms to submit printed price lists of their components to the ECMA printing office, which are then published as an appendix to the quarterly specifications manual. The second rule provides that no new manufacturer of electrical components can join the ECMA unless it receives a vote of two thirds of a standards committee that is composed of ECMA members and that passes judgment on the quality of the applicant's components. Currently the committee is composed of twelve members, five of whom make steel conduit. Antitrust challenges are lodged against both rules.

Both rules would ordinarily be challenged under the rule of reason, since both are ancillary to a legitimate joint venture. Further, both have arguable efficiency explanations. The price list rule facilitates bid preparers in determining not only specifications but also prices. The membership rule ensures that only manufacturers of quality products can join the venture. Thus if either rule is to be condemned, the challenger must make some kind of market power showing.

The appropriate market power inquiry differs, however. The threat of posted price lists comes principally from possible collusion. In order to assess the threat one must know the market share of any particular product, such as conduit, that is controlled by the venture overall; but the internal structure of the industry is also very important. For example, if there were only three manufacturers of double-pole switches and all three submitted their price lists, the

risk of collusion would be quite substantial. By contrast, if all 650 members manufactured switch plates, the risk of collusion would have to be judged as very small, n233 In sum, then, a competitive analysis of the rule **[*93]** permitting firms to publish their price lists requires, first, a showing that the venturers in the aggregate had market power in the various products controlled by the venture. Second, it requires an analysis of the internal structure of the industry indicating the risk of collusion.

The exclusion rule would be treated differently. Suppose that the inventor and new manufacturer of plastic conduit should apply to join the venture and have its product included in the specifications manual. The committee votes seven to five to admit, thus falling short of the two-thirds requirement. All five of the steel conduit manufacturers voted against membership, while the other seven voted in favor.

Assuming the dominant position of the venture as a whole, the market power inquiry as to this question must consider (1) whether the exclusion rule facilitates collusion, and (2) whether the exclusion rule permits members committed to an established technology or way of doing business to prevent the growth of a rival and perhaps superior technology or mode of doing business. As to the first question, internal structural issues are just as relevant as they were to analysis of the price list publication rule. Cartels can certainly be facilitated by excluding rivals from market access, but collusion must be likely in the first place. If the three members of a trade association exclude a price-cutting forth from market access, our eyebrows are raised. But if an association of 35,000 dentists in a state votes to discipline one member for ethical violations unrelated to pricing, facilitation of collusion is not likely.

If our concern is not collusion but rather exclusion of competing technologies or ways of doing business, the internal market structure of the venture is much less important and may be irrelevant. For example, the makers of steel conduit in the hypothetical have a common goal: protection of their market share from the incursions of a threatening innovator. None of the cheating problems typically associated with the cartel apply. Further, enforcement of the rule is an "associational" rather than individual act. Once the anti-plastic conduit decision is [*94] made, it really does not matter whether the body that made the rule contains three manufacturers of steel conduit or 3000. The exclusion is caused by a single entity, the association, and only the association can change it. n234

In such cases, the small size of individual venture members is of no consequence, particularly if the venture has the power to enforce exclusionary rules. The Tenth Circuit failed to see this in the VISA case, n235 when it concluded that, because Visa had numerous members anticompetitive exclusion would be unlikely or even impossible, n236 In this case, however, the challenged exclusion was a formal associational rule that forbade VISA members from issuing a competing card. Because the rule was enforced at the system level and a violation was readily detected (no one could secretly issue a competing card, such as Discover or American Express), whether Visa had ten members or 10,000 members was of no consequence. Each individual Visa member would be better off in a world in which it did not have to compete with a more aggressive, lower cost rival, and the rule could easily be enforced by the association. [*95]

D. Market Share Thresholds at Network Level

In the short run, the principal advantage of a joint venture is transactional economies or economies of scale or scope. Presumably, these economies could not readily accrue to single firms in the position of the joint venturers, although they could certainly accrue to larger firms. In some "network" joint ventures such as Associated Press or VISA/MasterCard, these economies may be "global," in the sense that costs decline continuously as the output of the venture grows. However, in other network joint ventures such as NCAA or the NFL, there are certainly diseconomies resulting from large size. For example, if the NFL had 5000 members, organizing playoffs and a Superbowl would be a gargantuan undertaking. Furthermore, the quality of the players, a limited resouree, would probably decline since so many would have to be recruited.

This creates an antitrust quandary. If the market share of the VISA venture exceeded fifty percent and costs declined through the entire output range, then no similar venture could match its efficiencies. By contrast, if the NFL had a 50% share of some properly defined market, there might be room for numerous, smaller football conferences that were equally efficient.

The market power query also begins with the proposition that the joint venture is not a firm, but rather a combination of firms. As a result, market power is more readily created and brought to bear. n237 Further, even though the market may be diffuse at the member level, joint ventures create opportunities for oligopoly performance at the system level, particularly if they are not restrained by aggressive internal competition.

As a result, concerns about exercise of market power are greater than normally considered appropriate for analyzing single-firm conduct, and more akin to those that apply to mergers. Presumptively, dismissal of a rule of reason complaint seems warranted if the market has a system level HerfindahlHirschman Index ("HHI") reading of less than 1800, and the share of the market controlled by the venture is less than 25%. n238 At an HHI of 1800, the market has the equivalent of **[*96]** roughly three equal size firms or ventures, and a 25% market share leaves room for three substantial competitors. n239

VI. Free Rider Concerns

Joint venture compulsory access rules invite legitimate concerns about free riding. Firms participate in ventures because they anticipate gains, but participation involves significant risks. Indeed, many activities are undertaken by joint ventures precisely because the risks are so great that no firm acting alone wishes to bear them. Compulsory access rules would destroy the incentives to form ventures if they permitted firms to avoid joining at the time the venture is formed, when risk is high, because they know they could participate later, when the risks have been reduced or eliminated, n240 Any profit-maximizing firms would wait-and-see, leaving others to commit their resources during the initial period of high risk and presumably low or negative return. As a result, the venture would never be formed at all.

But free rider concerns do not become decisive simply because they can be articulated, n241 Further, often practices that **[*97]** are labelled as free riding are nothing more than competition. This section develops these propositions:

1. Free riding must be distinguished from vertical integration, product complementarity, or other relationships among firms. Properly defined, free riding is an output reducing strategy. For example, people like butter with their bread. As a result, bakers sell more bread because of a dairy industry in which they have made no investment. To call this phenomenon "free riding" serves no policy end, however. First, such product complementarity is ubiquitous and desirable. Second, the output of both bread and butter is larger because each "free rides" on the other in this fashion.

2. Free rider concerns are most serious in "closed" ventures -- that is, ventures whose membership is determined at the onset and who generally follow a policy of not admitting any subsequent members.

3. Free rider arguments become much harder to sustain when a venture is "open," pursuing a policy of continuing to accept new members in the future, but excluding on a selective basis. In these cases, free rider arguments do not necessarily have to be dismissed out of hand, but they should be scrutinized very closely and the presumption should be against them. In general, free rider claims should be disregarded when the effect of admission of the excluded firm is to increase output within the venture, with an exception only for clear cases of misappropriation of intellectual property or other property rights.

A. The Relation Between Free Riding and Output

Free riding occurs when a firm is able to capture the benefits of investment that another firm has made without paying for them. In antitrust the now-classic example of the free rider **[*98]** is the dealer in a manufactured product who rides on the promotional or service efforts of other dealers.

For example, the full service computer dealer may have, among other things, an expensive showroom, trained personnel demonstrating computers and assembling optimal packages, seminars for prospective purchasers. The free riding dealer down the street has a cheap warehouse, untrained minimum wage personnel, and stacks of computers in boxes. Customers will go to the full service dealer and obtain the information they need to make a wise choice; then they will go to the free rider to make their purchase at a lower price, n242 Likewise, the firm that "invents around" a patent, making a cheap copy of something that required much more investment to develop in the first place, is a free rider.

Free riding in both of these examples is economically inefficient because it leads to reduced output. In the case of vertical restraint, the dealer unable to capture the cost of its promotional efforts will have less incentive to invest. To the extent the full service dealer must compete with free riding dealers on price, the only way the full service dealer can survive is by cutting services itself. When that happens, overall demand for the supplier's product goes down. Once customers are unable to obtain any point-of-sale educational services, they will shop for a different brand, n243

In the case of the firm that "invents around" another's patented invention, the more tolerant the patent laws are of such evasions, the fewer patenting returns. The firm who knows that its innovations can be cheaply and legally duplicated may decide not to invest very much in innovation, and as a result, less innovation overall will take place. If innovation itself is output increasing, as we assume it is, then the result of widespread cheating on patents will be to reduce output.

This emphasis on output effects is important, because it distinguishes between free riding as a problem for competition policy and simple product complementarity. Bakers are in a sense "free riders" on dairies that churn butter, because the bakers are trading with the knowledge that people like bread **[*99]** with their butter; or, to put it another way, the dairy's investment in butter production results in the sale of more bread.

But if this phenomenon is to be labelled "free riding," it is not the kind of free riding that is of any concern to antitrust policy or law, for it results in increased rather than decreased output. Bread production actually stimulates demand for butter, and vice-versa, notwithstanding the fact that each producer takes a "free ride" on the investment made by the other.

In assessing the output effects of free riding, one must also distinguish long-run from short-run output effects. In the shortrun, output actually increases when the "no frills" dealer sells at a lower price, because lower prices attract more customers. Likewise, output often increases when a patentee's rival is able to invent around the patent; the product at issue will be produced under a certain amount of competition. Nevertheless, free riding tends to reduce output because the long-term effect is to give the full service dealer and the innovating patentee less incentive to make future investments. If free riding by "no frills" dealers cannot be eliminated, then the incentive to invest in a full service dealership will be reduced. The eventual result will be fewer consumer services in that brand overall, and then consumers will respond by buying less. Likewise, if patents can easily be evaded by rivals, the incentive to invest in inventions that require patent protection will be greatly reduced. The result will be less investment in research and development.

But this need to distinguish between short-run and long-run output reductions makes true free riding difficult to identify, and its efficiency effects hard to measure. Free riding claims are easily asserted, but valid claims must be distinguished from those that are frivolous, or those that confuse free riding with simple product complementarity. Antitrust policy should encourage joint ventures that are efficient, that is when they enlarge output. But the antitrust tribunal must also consider the impact of its decision on the formation of future ventures. A decision that tends to increase the output of the particular venture in front of the court may, in fact, result in reduced output over the long haul if the decision itself dissuades other firms from forming similar ventures.

B. Free Riding and Closed Ventures

Suppose three out of four automobile manufacturers decide to engage in joint development of a new, more fuel efficient [*100] engine. The research will be costly, and there is a substantial risk that it will produce nothing. Three of the four manufacturers decide to participate, but the fourth declines, assessing the risks as too high in proportion to the anticipated returns. A few years later the research proves successful, and the new engine looks like it will become a reality. Now the fourth automobile manufacturer asks to join, and the three venturers decline. In this case, antitrust laws should generally not afford a remedy. If the four firms each knew in advance that they could have waited to see if the venture succeeded and would have a right to join at that time, then none would have been willing to take the initial risk. The venture would never have been formed.

Holding that the closed venture has no duty to deal is presumptively similar to holding that it is not illegal for a single firm to dominate a market. That is, the status of being a monopolist is not illegal. However, additional

exclusionary acts other than the refusal to take on new members should generally be subjected to ordinary antitrust analysis.

Compulsory access is arguably an appropriate remedy if the venture presents a substantial risk of unlawful collusion among members. On the one hand, forced accommodation of additional firms can make a cartel less stable or simply break it up. On the other hand, this conclusion cannot be assumed; the entry of only one additional firm is not likely to break up a cartel, and more direct remedies would seem to be superior, n244

In sum, in the absence of collusion or an exclusionary practice such as patent misuse or predation, there is very little reason for antitrust laws to force admission into ventures that were intended to be closed from their inception.

C. Open Membership Ventures

An open-membership venture is one in which new members are admitted after the venture is initially created, and may be continuously admitted on an ongoing basis. Most trade associations are of this type, and so are "network" joint ventures **[*101]** such as the VISA and MasterCard bankcard systems, n245 Other joint ventures, such as the National Football League or the Big Ten Football Conference, may have highly restrictive membership policies, but they do occasionally admit new members upon application and approval by existing members, n246

By contrast to closed-membership ventures, antitrust policy is appropriately concerned with the selective membership policies of open membership ventures, provided that the venture controls a sufficient share of a properly defined relevant market, n247 Markets are artificial

creatures, and open-membership ventures with market power can effectively determine their workings or select their participants. For example, exclusion from membership in a real estate multiple listing service is practically tantamount to exclusion from the real estate profession, n248 When the open-membership joint venture has substantial market power, selective exclusion may become a device for cartelizing a market -- as, for example, when the multiple listing service rejects real estate firms that have a reputation for reducing their commissions. They may, however, become a device for restraining the development of a competing product or process -- as, for example, when a society dominated by steel conduit manufacturers reject a firm simply because it ['102] makes an alternative product, e.g., plastic conduit, that threatens the profits of the existing members, n249

To be sure, even open-membership joint ventures may be subject to free riding. When the venture pursues a general policy of taking on new members but selectively excludes a few, the traditional free rider argument becomes far more strained. For example, Visa generally permits new banks or financial institutions to join, but has a by-law that excludes offerors of competing charge cards, n250 If this policy is to be defended by a "free rider" argument, there must be some basis for concluding that issuers of competing cards are free riders in a way that other financial institutions are not. Further, the court must be able to distinguish between free riding concerns with the simple desire to avoid competition.

For open membership ventures, the free rider argument that the new applicant did not incur any risk at formation time is irrelevant. None of the subsequently admitted members had to incur these risks, but most are admitted nonetheless. To be sure, this does not undermine all free rider arguments. There still may be claims of

misappropriation of intellectual property rights. Some firms may be in a particularly good position to use the joint venture's intellectual property in a way that shifts sales away from the venture product and toward the competing product. For example, suppose that one large computer maker offers a proprietary processing chip. A joint venture of smaller computer manufacturers have developed a superior chip, which they sell to their members, but the process for making this chip is subject to some trade secrets. The large firm now seeks access to the venture so that it can learn the trade secrets and apply them to its own chip.

The large firm is a free rider in this case because the impact of its entry into the venture will be reduced output of the venture's computer chip. The large firm does not intend to use the joint venture's chip at all, but merely to steal some technology so that it can improve its own chip. The free rider claim is legitimate because if the large firm is admitted the result will be reduced output within the venture. **['1031**

But such claims must be distinguished from the much more common reason underlying exclusion of competitors: namely, that admission of the aggressive applicant will steal market share from existing members. For example, suppose the local real estate industry has a comprehensive multiple listing service, and charges fairly constant seven percent commissions on real property sales. New applicants for multiple listing membership are routinely accepted, but when a new firm advertising five percent commissions applies, it is rejected. In this case, admission of the new applicant would increase the output of the multiple-listing venture as a whole. That is, with the new low commission member in the venture, the price of property would be lower and more would be sold. However, the more relevant impact for existing members is that, although venture-wide output would be increased,

they could anticipate that their individual outputs would be decreased. Seller's would opt for the firm charging the five percent commissions, n251

The VISA/Discover case presents the same situation, n252 Historically, the Visa joint venture had an open membership policy for qualifying financial institutions. In 1976 the Visa board admitted MasterCard issuers to be members, and eventually more than 90% of the venture's members issued both cards, n253 In the 1980s, however, Visa was faced with the development of rival Discover Card, a proprietary general purpose charge card. n254 After an initial period of trying to drive Discover out of the market by denying it access to merchant processor terminals, n255 Visa proposed to admit Dean Witter, Discover's owner, into the venture, but to convert Discover into a VISA card. n256 Dean Witter declined that offer and applied for membership in Visa, intending to issue VISA as well as Discover cards. n257 The Visa board then adopted a bylaw designed to exclude from Visa any firm that offered a competing charge card. n258 **['104]**

When Discover charged a Sherman Act violation, Visa raised a "free rider" defense. In this case, however, Discover's entry into the Visa venture would have increased rather than decreased the output of VISA cards. The fear was not that Discover might steal certain secrets, and then apply them to Discover in such a fashion as to make Discover more appealing than VISA. Rather, the fear was that Dean Witter would be able to market a "package" including both a proprietary Discover Card and an Interbank VISA card, in much the same way that most Visa members packaged a VISA and a MasterCard. That is, Discover and VISA would be offered as complimentary products, and overall output of both would increase.

Although a Discover/VISA package would increase rather than decrease the output of VISA cards, and presumably of VISA transactions, existing members opposed it for the same reason that the multiple listing members in the earlier hypothetical resisted admission of the price cutter. Although venture output as a whole would increase, all of the gains would accrue to the new member, and the new member even threatened to steal market share from the existing firms. n259

One of the best indicators of this fact is that the Visa venture so willingly accommodated MasterCard, even though it, too, was a competing card. The ability of member financial institutions to offer a MasterCard/VISA package was attractive to consumers as well. But the all important difference between accommodation of MasterCard and accommodation of Discover is that, each existing member was free to offer a MasterCard. Thus, admitting MasterCard increased the output of the venture as a whole, but the output increase was more-or-less evenly divided among all banks that wished to offer both cards.

In sum, the difference between MasterCard and Discover is the difference between economies that accrue to oneself and economies that accrue to one's rivals. All economies benefit consumers. However, business firms see the matter differently. Although they benefit from economies that they are able to claim for themselves, they are generally injured by economies **['105]** that accrue to rivals. That is why, for example, they look eagerly for efficient joint ventures for themselves, but look for ways to challenge the joint ventures of their competitors, n260

When assessing free rider concerns, one must look at the long-run, and Ex ante concerns are particularly important. Judicially enforced admission of rivals may destroy the incentive to form a joint venture in the first

place. This argument becomes strained, however, in the case of a venture like Visa, which has a policy of admitting virtually all who apply. More importantly, it is not "free riding" when a new entrant either (a) threatens to undermine collusion among existing members or (b) threatens by its own innovations to force more aggressive competition within the venture. Both of these outcomes tend to increase rather than diminish output.

There may be more particularized intellectual property concerns. For example, Visa may have developed a new method for processing transactions more efficiently than alternatives. If Dean Witter becomes a Visa member it would acquire the secret, and may then be in a position to apply the process to Discover as well as Visa transactions. Such concerns, if proven, are legitimate; but they cannot simply be assumed under some general claim of free riding.

In sum, the real problem in the VISA case is not that the VISA card and the Discover Card are competitors, n261 The problem is that they are complements, like bread and butter or hardware and software. The real injury to current VISA issuers is that Dean Witter will promote a VISA/Discover package that will be either more attractive to consumers than other alternatives on the market or will have lower costs. In that case the result will be increased demand for Visa's cards, but the increase will accrue to the owner of Discover.

Finally, free rider defenses should be rejected when the firm that controls the input is able to sell, rather than give away, the good or service that is subject to the free ride. n262 For **['106]** example, in the context of vertical restraints, free riding is a problem because the typical dealer is not in a position to charge customers separately for the point-of-sale services that make the full service dealership valuable to suppliers and consumers. Rather, the cost of the services is

built into the full service dealer's package price. However, if the dealer could price the service and the product separately, then free riding would not be a problem. The customer already will have paid for the services, and both the full-service dealer and the discounter could compete for the product strictly on price, n263

In sum, in order for an open-membership joint venture to maintain a free rider defense it must show that: first, the claimed free rider is in a position to appropriate intellectual property or other rights in a way that threatens to reduce the output of the venture in the long-run; and second, the particular property right at issue cannot reasonably be sold, rather than given away, to the firm against which free riding is claimed.

VII. Less Restrictive Alternatives

One of the most important doctrines of the rule of reason is that the restraint must be no broader than necessary to achieve its legitimate goals, n264 Indeed, this "overbreadth" rule was part of the common law of trade restraints long before the Sherman Act was passed, n265 The rationale is simple enough: if ['107] an agreement with any significant potential to harm competition is justified by its potential for efficiency, then the agreement must be tailored in such a fashion as to do the least harm possible to competition without giving up the efficiency gains, n266

Assuming the claim is legitimate and that free rider concerns are substantial, one naturally asks: why not simply pass a rule that issuers of competing cards cannot be board members. If such a rule would alleviate the concerns about access to intellectual property while doing far less injury to competition than a rule excluding Discover from Visa

altogether, then antitrust should condemn the broader rule as long as the defendant is unable to show that the narrower rule will not work. n267

Of course, just as efficiency defenses or free rider claims should not be accepted simply because they are offered, so too not every suggestion of a less restrictive alternative will prove workable. But business firms often have great flexibility to create or preserve efficiencies by a variety of means. Once the plaintiff offers what reasonably appears to be a less harmful but equally efficient alternative to a challenged restraint, the burden should shift to the defendant to show why the offered alternative is not workable, or why it would not achieve the efficiencies claimed for the challenged restraint. **['108]**

VIII. The Appropriate Scope of Access Claims

A. Distinguishing "Universal" from Limited Access Rights; "Essential Facility" Claims

A troublesome feature of "network" joint ventures is that, although the decision to exclude is often anticompetitive, clearly not everyone has a right to participate. Consider, for example, two complex ventures whose ongoing cooperation is necessary to deliver the venture's product: AP and the NFL. AP was thrown open by the Supreme Court's decision to any newspaper that wanted to apply, n268 But surely an antitrust court should not go so far as to hold that any qualified group of eleven strong athletes plus a coach should be permitted to join the NFL. n269 Why shouldn't IBM or Ross Perot simply be able to put together a group of good players and then insist on a right to join the NFL? What distinctions between Visa and the NFL as ventures requires open access in one but not the other, and can antitrust develop workable rules for giving effect to these distinctions?

Antitrust's purpose is not to define the appropriate scope of joint ventures, but rather to identify and condemn restraints on competition. Apropos of this, a few things seem important. First, NFL football teams are not in any substantial sense economic competitors with each other. Of course, they do compete in some ways. If both the Cowboys and the Dolphins are playing at the same time on different television channels, they may compete for television revenue. But in the main, each team seeks gate receipts in its own town, and competes for television or radio revenues with other forms of programming. Second, although the NFL has severe access rules that deny new membership to just about everyone, the rules are not defined in terms of impact on competition with existing members. Indeed, when they are defined in this fashion, antitrust may intervene, n270 The Associated Press case provides a good **['109]** illustration: n271 the AP rule admitted all applicants generally, but imposed more restrictive membership rules on competing newspapers in the same town. If AP's domination of the wire service gave the first newspaper in town to become a member a substantial competitive advantage over other newspapers in that town, and if these others were then unable to join, the result could be a substantial opportunity for the exercise of market power. In sum, the thing being challenged in cases such as Associated Press and VISA is not the venture's right to limit its size. Rather, the challenge is to a policy of not limiting size as a general proposition, but then discriminating against competitors.

Thus if Visa were to decide that, for administrative reasons, it would be best to cut off membership at 600 and admit no additional applications, antitrust would have no complaint. Nothing is gained by forcing either firms or joint ventures to grow inefficiently large, and antitrust courts would not be good judges of optimal scale. Likewise, if Visa had set strict financial requirements that only a few hundred

banks could meet, it is hard to see the basis of an antitrust complaint. The problem with the rule that was actually challenged in the VISA case is that it admitted financial institutions generally, but imposed a heavy premium on competition as such.

Antitrust concern with restraints on competition generally entails that concerns about "essentiality" are misplaced. n272 The essential facility doctrine defines access from the applicants' perspective by asking whether access to a market really requires access to a particular facility. But focusing on essentiality tends to undermine antitrust's concern with competition. The concern of antitrust is not with the abstract ability of each firm to participate in a market. Rather, it is concerned with the ability of firms to raise price above the competitive level and hold it there for extensive periods of time. **[*110]**

The essential facility doctrine developed out of cases in the regulated industries, n273 and is infected by the regulated industries' preference for universal access. But defining antitrust access rules in terms of essentiality is both over and underinclusive. First, it is over-inclusive to the extent it suggests that weak or inefficient firms have some right that competitors give them a helping hand. In this sense, the essential facility doctrine is a relic of the populism that infected antitrust in earlier eras.

Second, the essential facility doctrine is under-inclusive because firms may acquire considerable power to raise price above the competitive level without acquiring anything like the ability to exclude everyone. Indeed, many monopolistic pricing strategies contemplate a fringe of firms remaining in the market, n274 Strictly speaking, almost nothing is essential. For example, if a truly large firm such

as General Motors wished, it undoubtedly has the resources to develop a network of competing professional football teams much like the NFL.

Likewise, an essentiality requirement misses the point when admission of the applicant would have no impact on competition, or when the venture is already behaving competitively. For example, the NFL may be an "essential facility" for a team wishing to play televised professional football. But supposing Iowa City's collection of paid football players, the Buccaneers, wished to join the NFL, the essential facility doctrine would not come to their rescue. There would be no more competition in the NFL after the Buccaneers were admitted than before, n275 Further, suppose that the highly competitive market for professional truck rivers is governed by the requirement that every operator have a chauffeur's license. A local government, acting arbitrarily and without any authorization from the state, denies one applicant a license, n276 This local government might be liable **[*111]** to the applicant under many legal rules, but antitrust's essential facility doctrine should not be one of them. The market is no less competitive as a result of the applicant's exclusion, n277

In any event, the history of Supreme Court decisions on joint venture access rules makes a very poor case for application of any modern-day essential facility doctrine. The Supreme Court's decree in Terminal Railroad, often cited as the first "essential facility" decision, n278 permitted everyone either to be a customer of the facility or else an owner, on nondiscriminatory terms. Essentiality was never required. Under the Court's decree the defendant's were entitled to give every applicant a right to join, whether or not it could show essentiality. Of course, the facility may have been essential for everyone, n279 But in that case the

decree simply reflected the judiciary's traditional common *law concern that common carriers and other monopoly* public utilities be obliged to accommodate everyone, n280

The Associated Press case, also identified with the origins of the essential facility doctrine, was not about access to an essential facility at all. It was about an explicit restraint on competition. Once again, no one was required to show essentiality. The Supreme Court merely held that in taking on new members AP could not discriminate against newspapers who competed with an existing AP member, n281

In sum, the antitrust laws are concerned, not with joint venture access rules as such, but rather with restraints on competition. In this sense, antitrust analysis of joint ventures is no different than antitrust analysis of any other business practice. For example, antitrust interferes with price fixing, not because it believes courts are better than market participants **['112]** at setting prices, but because firms are not permitted to eliminate competition as a factor in the price setting process.

B. Intersystem Rivalry Defenses

When speaking of joint ventures and competition, it is sometimes useful to distinguish between competition at the member level and competition at the system level. For example, at the system level MasterCard is a general purpose bank charge card that competes to one degree or another with VISA, Discover, American Express, or Diners Club. By contrast, at the member level MasterCard consists of several thousand card issuing banks that also compete with each other on such things as annual fees, interest rates, the "grace period" for bill payment, and frills such as flight insurance, extended product warranties, theft protection, and the like.

Not all ventures face competition at both levels. For example, if the relevant market is televised professional football, the NFL probably has no system level rivals. Likewise, in many ventures that are competitive at the system level there may be very little competition in the joint venture product at the member level. Indeed, members of joint ventures need not be competitors at all. Sometimes they are vertically related firms, manufacturers of complimentary products, n282 or sellers in different geographic markets, n283

Antitrust's concern with competition is quite general, and both member level and system level competition falls within its domain. One must not confuse competition with rivalry, however. If Associated Press should succeed in driving weaker UPI plus other wire services out of business, it would have no rivals. But that fact alone says absolutely nothing about the impact of AP's dominance on competition. The market may actually be more competitive if AP is the only survivor. First, if AP is a natural monopoly, its costs would be lower than the costs facing any combination of two or more firms in the market. In that case, price could actually be lower when AP is the **['113]** only venture than when AP co-exists with LIP and INS. Second, member level competition can make system level competition superfluous.

Antitrust's concern is with economic competition, and although the number of rivals is sometimes important in determining the degree of competition, it is not always decisive. What is decisive is the relationship between a firm's prices and its costs when the firm is taking advantage of all available efficiencies. In answering that question the number of systems may be quite irrelevant, provided that intrasystem rivalry is unrestrained, n284 The system itself has no outside owners; its owners are its members. As a result it cannot generally make money by selling to itself at a

monopoly price. It cannot sell to others at a monopoly price unless its members agree with each other to reduce their output of some good or service -- something that the antitrust laws should forbid them from doing.

Suppose, for instance, that MasterCard were the only bankcard system, and that its several thousand members occupied 100% of a properly defined relevant market. However, these members compete vigorously with each other both in card member terms and in the interchange fees that are passed on to merchants. We would expect competition to eliminate monopoly profits for all the various services and transactions relevant to the offering of an interbank charge card.

Suppose now that the DOJ, thinking MasterCard an unlawful monopoly, were to split it into two entirely separate ventures, called MasterCard and VISA. There would now be cards bearing two different names. But if competition was unrestrained before this breakup, we would not expect any impact at all on the pricing of services, the nature of the services offered to either consumers or merchants, and the like. Indeed, if there were substantial economies of scale in the organization of **['114]** an interbank general purpose charge card venture, the costs of two different systems might go up, and prices would go up as well.

The relationship between VISA and MasterCard in the United States is sometimes cited as evidence that intersystem rivalry benefits customers. Before 1974, VISA and MasterCard had exclusivity rules that prevented any financial institution from offering both cards. However, in response to a lawsuit from a bank wishing to offer both, n285 the rule was set aside, n286 Today the vast majority of

members offer both. Visa subsequently contended that the result of the VISA/MasterCard duality was that competition between the two cards was significantly diminished, n287

But any diminution of competition results, not from duality itself, but from the fact that within the ventures issuing banks are permitted to fix bank "interchange" fees that merchants were charged for accepting VISA card. n288 In the face of unbridled competition, there is no reason for thinking that duality would increase the price of bank charge cards.

Indeed, sometimes duality can increase competition significantly. Consider Discover's entry into Visa. The all important difference between the duality of VISA and MasterCard, and the duality of VISA and Discover, is that in the former union every member of Visa was permitted to offer a MasterCard, and vice-versa. By contrast, the Discover Card is proprietary, so only Dean Witter can issue it. The impact of Dean Witter's ability to package a VISA card and a Discover Card will be a more attractive consumer offering. Other Visa members who wish to retain their market shares will have to improve their own offerings or cut price in order to retain their customer base.

The incentives from Discover's perspective are only slightly different. Dean Witter would control 100% of Discover ['115] transactions and some small percentage of Visa transactions -- let's assume 5%, which it might acquire by competing very aggressively for VISA card holders. For any future transaction, if that transaction is made with a Discover Card, Dean Witter will be sure to get it. By contrast, if it is made with a VISA there is only a 5% chance that Dean Witter will get it, since 95% of VISA cards are controlled by other members. As a result, Dean Witter has almost the same set of incentives to push Discover at the expense of VISA as it had before it joined the venture. In

sum, then, Dean Witter's admission into Visa has two effects on competition: (1) competition among VISA issuers becomes more intense; but (2) competition between Visa and Discover remains virtually undiminished, or else it becomes more intense to the extent that other VISA issuers try to make Visa a more attractive offering than Discover.

Intersystem rivalry becomes more important if member level competition is inadequate. If the MasterCard joint venture closed itself to new membership when it reached a membership total of ten large banks, and these banks were behaving collusively or oligopolistically, then the development of alternative systems might force the MasterCard venture to behave more competitively itself.

To be sure, once Associated Press is thrown open to every newspaper that wishes to apply, then no one will be forced to develop a rival news wire service such as United Press International. n289 Some write as if compulsory access rules are seriously anticompetitive because they destroy the opportunity for increased system-level competition, n290 But that proposition is hardly self-evident. First, as noted above, increasing the number of systems does not necessarily increase the amount of economic competition at all unless intrasystem competition is restrained. Further, if scale economies are substantial, as they often are in network joint ventures, then multiplying networks may actually result in increased rather than decreased costs.

Second, compulsory access rules do not foreclose the development of alternative systems; rather, they simply give prospective entrants into a market the choice between joining an existing venture or starting out on their own. At the margin, the **[*1116]** firm will do what was most profitable, n291 For example, if the existing venture produced no scale economies or risk reductions and wielded no market power, a new firm might be indifferent as to whether it joined the

venture or struck out on its own. By contrast, if the existing venture was colluding, a new f'irm might be better off starting out on its own. It would be able to sell at the cartel price without having to worry about venture imposed output reductions. Alternatively, if the venture produced substantial scale economies then the rum would opt for the venture -- but the presence of such economies is good evidence that antitrust policy would not be well served by forcing alternative ventures.

Measurement of risk and economies of scale in a given situation is difficult if not impossible. No antitrust tribunal can look at a venture such as Visa and proclaim that the market has room for one, two or six such ventures of minimum optimal size. The value of compulsory access rules is then that they permit new firms constantly to test the costs and returns of operating within the venture against the costs and returns of pursuing alternatives.

For example, the aftermath of the Associated Press case was that, once compulsory access was put into place, AP quickly grew into the dominant wire service, and incipient rivals UP and INS languished, n292 But this is simply another way of saying that UP and INS would probably never have developed in the first place had it not been for AP's membership restrictions. Given the high fixed costs of producing news, and the infinite duplicability of a news story, AP was a natural monopoly. Any newspaper would have been better off participating in large, low-cost AP rather than smaller, more expensive UP or INS. To be sure, the growth of this monopoly might raise concerns about press freedom or the preservation of alternative news sources in a democratic society. But those are not the concerns of antitrust law.

When competition among venture members is vigorous, multiplying the number of systems cannot save resources unless we postulate that the costs of operating a single system are higher than the costs of operating multiple systems, and this certainly cannot be presumed. Multiplying the number of systems saves ['117] resources only if there is some reason for thinking that multiplying systems will increase the amount of competition. If decisions on price and output are already made by members behaving competitively, this is generally not the case.

Often multiplying systems will not increase rivalry even if the firms in the initial system are not competing. For example, suppose we simply divided the NCAA in half, placing half its schools in one football association and the other half in the other. Game schedules would have to be redrawn and there would be a re-alignment of team rivalries, but there is no reason for thinking that individual colleges would compete for advertising dollars any more aggressively than they do today under a venture that permits each college to televise as many games as it pleases. Changing the number of systems has no impact on competition when the relevant competitive decision occurs at the member level rather than the system level to begin with, and multiplying systems has no impact on member level market structure.

So encouraging a proliferation of systems is not necessarily in the interest of consumers at all. Further, claims made in litigation that exclusion will encourage system level competition are manifestly disingenuous, and ought to be ignored when they are made by the antitrust defendant itself. Consider Associated Press, where the Supreme Court condemned AP's policy of excluding second newspapers in towns that already had an AP member. Suppose that AP's principal defense was that the impact of the exclusionary rule was to facilitate the development of

alternative wire services, and that this would promote system-level rivalry.

If that were the principal effect of the exclusive policy, AP would never have adopted the policy. Like any profit-maximizers, AP's members would adopt the policy that maximized their own profits, which comes from minimizing the amount of competition with others, n293

IX. Administration of Antitrust Access Decrees

['118]

It is sometimes said that administration of joint venture decrees striking down exclusion rules requires courts to operate as regulatory agencies, or otherwise involves courts in ongoing administration for which they are not well suited, n294 Certainly courts must ensure that their decrees are capable of being administered, and complex antitrust decrees can yield difficult problems of administration. But in the range of antitrust decrees that need ongoing administration, administering joint venture membership policies hardly qualifies as the most complex.

Antitrust decrees are thought to be particularly difficult to administer, because they often require knowledge about markets that is simply not available to generalist federal judges. Defendants are ordered to do something that they would prefer not to do, and they will look for ways to do as little as possible, to delay, or to maximize their own position within the confines of the injunction without regard to the welfare of the injunction's beneficiaries. Administration of antitrust decrees is particularly difficult when the decree orders a firm to behave in an irrational matter, or when it orders a firm to set particular prices in areas where a great deal of discretion remains over such issues as proper rate of return or

allocation of costs. So, for example, the late Donald Turner once noted the difficulties that would inhere in any injunction ordering an oligopolistic firm to behave competitively. A large firm in a concentrated market is necessarily a price maker, and cannot be changed into a price taker merely by a court order, n295

But not all decrees are equally difficult to administer, and compulsory access decrees certainly need not be among the ['119] most difficult. The most difficult decrees to administer are those requiring a venture to adopt some brand new policy or to set a fair price for participation where the market has not made any prior determination of what that price should be. To return to a previous example, suppose three of four auto makers jointly developed a more fuel efficient engine and now a court erroneously decides that a fourth firm is entitled to be a late joiner, n296 The court orders the venturers to admit the fourth upon payment of the fair value of the risks undertaken and work done by the venture. Even experts could differ over a wide range on the question of the venture's value at the time entry is sought, the amount of compensation needed for risk, and so on. One of the inherent qualities of innovation is that, since the innovated product is new, little is known about its future demand, costs of production, difficulties that might emerge along the way, and so on.

In most compulsory access cases, however, the administration problem is far more tractable. For example, the district court in the VISA case condemned a rule under which the Visa venture would admit new applicants generally, but exclude those who issued a competing charge card. A decree tailored to the decision would simply order the venture to admit everyone on the same terms, without regard to whether they issued a competing card. n297

Important as it is not to underestimate the difficulty of enforcing even simple judicial decrees, in the range of antitrust injunctions this is not a particularly complex one.

Those who object to compelling joint venture inclusion on administration grounds must have in mind joint venture decision making where each membership application is subject to the whim of existing members or their board. This might include the venture that has no membership rules whatsoever except that an applicant must receive the affirmative vote of two-thirds of existing members. Some applicants receive twothirds while others do not, and one of those who fails alleges that its exclusion was anticompetitive. Now the court has the ['120] difficult job of determining ex post what motivated the exclusion.

To be sure, evaluating such decisions can easily become complicated. But such cases pose problems of administration only in the sense that all rule of reason antitrust cases pose such problems. For example, this kind of antitrust case is common when physicians are denied staff privileges by a board, some of whose members may have anticompetitive motives, n298 Antitrust under the rule of reason requires courts to make ex post judgments about the competitiveness or anti-competitiveness of the defendant's conduct. The result of the set of such judgments is a guide to what firms can do in the future. Problems of determining intent, or of inferring intent from consequences, can be difficult. But they are not different in kind from those that affect the administration of decrees in antitrust as well as other areas of the law. n299

In this area, the problem of complying with judicial decrees is generally more tractable than the problem of complying with the broad range of statutes. Unless the decree is badly drafted, it is generally more specific to the entity and situation upon which it is being imposed than

any statute is. Once the decree is issued, counsel for those upon whom the decree is imposed and for those whom it is intended to benefit must interpret it and make some prediction about how the court will interpret it. In cases of dispute, they can litigate or compromise. Which one they do depends largely on the care with which the decree was drafted, but a well written decree should have fewer loopholes and ambiguities than the general run of statutes, for the decree is not subject to the debilitating effects of the political process. **['121]** Further, the decree is accompanied by its own detailed "legislative history" -- namely, the judicial opinions that preface it.

In sum, the problem of complying with access decrees is not different in kind nor magnitude from the problems of complying with the law generally. Very badly drafted decrees, or decrees that force firms to behave in ways that are fundamentally irrational or inconsistent with the position in which they find themselves are bound to generate subsequent problems of interpretation and enforcement.

X. Conclusion: Exclusive Joint Ventures and the Rule of Reason

Most joint ventures presumptively create efficiencies that make application of the per se rule inappropriate, certainly to exclusion rules that are related to the operations of the venture. Of course, this does not imply that all exclusion rules require full rule of reason treatment; even efficiency creating joint ventures can be used as a front for naked collusion. n300 But that exception aside, analysis of exclusionary joint ventures ordinarily proceeds through a rule of reason analysis that begins with market power.

The stages in the rule of reason inquiry differ when the challenge is to exclusion rather than collusion. Fundamentally, however, the analysis is the same. n301 The main difference is that the Supreme Court has indicated, and with good reason, that labelling a joint venture refusal to deal as "naked" is not quite as easy as labeling an explicit output reduction or price fix as naked. Exclusive membership rules can be justified in a wider variety of circumstances than can price-fixing rules. Since rule of reason analysis proceeds through a serious of steps, looking for the most expeditious ways of deciding the case first, **['122]** this suggests a change in the ordering. Rather than looking first for a "naked" restraint, we look first for at least a minimal indication of market power. The Indiana Dentist and Northwest Wholesale Stationers decisions seem to compel this result, n302 The principal exception to this rule occur when the refusal to deal is clearly nothing more than a cartel facilitator, as it was in Trial Lawyers. n303 Such cases are ordinarily easy to identify, however. For example, in Trial Lawyers the concerted refusal to deal was directed at customers, and its only purpose was to force the customer to pay more.

Once a qualifying "agreement" has been found, analysis of joint venture exclusion rules should then proceed through this series of questions:

1. Can the joint venture refusal to deal be interpreted as serving any rational purpose other than facilitation of price-fixing? If not, the refusal is illegal per se; if yes, proceed to the next step. n304 As a general matter, concerted refusals directed at customers are highly suspicious and should ordinarily be regarded as naked. Concerted refusals directed at rivals are less suspicious because they may result from discipline, good faith determination that the excluded firm offered substandard products or services, or products or services that are

inconsistent with the venture, or that the excluded firm was a free rider.

2. Does any aspect of the challenged venture or the exclusion rule or practice being challenged **['123]** threaten to reduce output or raise prices in some properly defined relevant market? In addressing this question, the court must first define relevant markets under ordinary antitrust principles for any market level at which competition might be threatened, n305 If the market share represented by the venture as a whole is so small that no anticompetitive output reduction is possible, then any agreement surviving the step one inquiry should be dismissed, n306 If power is found, proceed to step three.

3. Does the exclusionary practice or rule under challenge arguably further legitimate efficiency goals articulated by the venture? If not, the exclusive rule or policy should be condemned unless it survives the step four inquiry. For purposes of analysis under this step, "legitimate efficiency goals" means that the rule must be shown to increase venture-wide output for the existing venture. The reduction of competitive incentives for future similar ventures is a free rider concern, and is addressed in step four. In considering the impact on venture-wide output, the tribunal should compare the venture's output when the applicant is excluded, with its output after the applicant is admitted, including the output of the new member itself. A rule should not be deemed efficient simply because it enlarges the output of one or more particular members, or maximizes the output of those firms already in the venture. For example, the insurance trade association's decision to stop collecting statistical data for certain kinds of losses should be evaluated for its effect on the output of the insurance industry as a whole, not for its effect on the output of insurers who do not wish **['124]** to write the kinds of insurance which the excluded statistical data would have

supported. Likewise, in the VISA case the decision to exclude issuers of competing cards such as Discover should be evaluated for its impact on total VISA customers or transactions after Discover becomes a VISA issuer, not for its impact on existing members who may lose customers or transactions to the new member. If an exclusionary practice or rule increases venture-wide output, it should ordinarily be regarded as legal. If not, it is presumptively illegal unless the defendant can make the showing in step 4.

4. An exclusionary practice or rule that reduces venture-wide output in the venture at hand may nevertheless be saved from illegality if free rider concerns are sufficient to produce substantial disincentives to creating similar ventures in the future. In the case of closed-member joint ventures (i.e., joint ventures that have not expanded beyond their initial membership), there should be a presumption in favor of articulable free rider concerns, including the concern that a rule permitting late comers to join without undergoing entry level risks will deter future similar ventures. In the case of ventures that have generally open membership policies but that exclude current applicants selectively, this particular free rider argument will not work; indeed, the fact that acceptance of the new member increases venture-wide output should be regarded as strong evidence that free rider concerns are insubstantial. If free rider concerns are nevertheless claimed, they should be explicitly defined and proven.

5. Even if free rider concerns are found to be legitimate, the plaintiff can rebut by showing less restrictive alternatives that will alleviate the **['125]** concerns and yet permit membership, n307 These alternatives may include an entry fee designed to compensate existing members for risk or other losses that flow from their own prior membership, n308 Any substantial propensity toward collusion at the member level should count heavily against the venture's

exclusion rule. Forced accommodation of new members can quickly break down a cartel.

Finally, on questions of standing, antitrust injury, and defenses:

6. Standing should generally be limited to firms that compete (or will compete after admission) with at least one joint venture member. None of the anti-competitive rationales for joint venture exclusion discussed in this article have any application to excluded firms who do not compete with the venturers, n309 At the same time, defenses of the nature that exclusion is competitive because it encourages intersystem rivalry should be rejected. If the principal effect of admitting an applicant to the venture is to diminish the likelihood of intersystem rivalry, the venture that did not admit the applicant would be acting irrationally.

FOOTNOTES:

Nl For a general overview of the antitrust law of joint ventures, see Herbert Hovenkamp, Federal Antitrust Policy: The Law of Competition and Its Practice section 5.2 (1994). The multiple actor requirement excludes joint activities by wholly owned subsidiaries of the same parent, or by other firms related by common ownership; that is, an enterprise carried on by two branches of the same firm is not a "joint" venture, as far as antitrust policy is concerned. See *Copperweld Corp. v. Independence Tube Corp, 467 U.S. 752 (1984);* Phillip E. Areeda, Antitrust Law paragraph 1463 (1986).

n2 As in *United States v. Penn-Olin Chem. Co., 378 U.S. 158 (1964)* (corporation); and *United States v. Terminal R.R. Ass'n, 224 U.S. 383 (1912)* (corporation) -- see *State v. Terminal Ass'n of St. Louis, 182 Mo. 284, 81 S.W. 395 (1904).*

n3 As in *Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 301 (2d Cir. 1979)* (contractual arrangement between Kodak and GE), cert. denied, *444 U.S. 1093 (1980).*

n4 An input is anything the firm uses or consumes in the production or distribution of its product.

n5 For recent literature, see Thomas M. Jorde & David J. Teece, Antitrust, Innovation, and Competitiveness (1992); Thomas M. Jorde & David J. Teece, Acceptable Cooperation Among Competitors in the Face of Growing International Competition, *58 Antitrust L.J. 529 (1989);* Thomas M. Jorde & David J. Teece, Innovation and Cooperation: Implications for Competition and Antitrust, 4 J. Econ. Persp. 75 (1990); Thomas M. Jorde & David J. Teece, Innovation, Cooperation, and Antitrust: Balancing Competition and Cooperation, 4 High Tech. L.J. 1 (1989); Carl Shapiro & Robert D. Willig, On the Antitrust Treatment of Production Joint Ventures, 4 J. Econ. Persp. 113 (1990); Gene Grossman & Carl Shapiro, Research Joint Ventures: an Antitrust Analysis, 2 J.L. Econ. & Org. 315 (1986); Janusz A. Ordover & Robert D. Willig, Antitrust for High-Technology Industries: Assessing Research Joint Ventures and Mergers, *28 J.L & Econ. 311 (1985).* An earlier treatment that has almost become a classic is Joseph E. Brodley, Joint Ventures and Antitrust Policy, *95 Harv. L. Rev. 1521 (1982).*

n6 *United States v. Trans-Missouri Freight Ass'n, 166 U.S. 290 (1897).* See discussion infra text accompanying notes 74-94. For an extended critique, see Herbert Hovenkamp, Enterprise and American Law, 1836-1937 at ch. 12 (1991).

n7 See *NCAA v. Bd. of Regents of the Univ. of Oklahoma, 468 U.S. 85 (1984).*

n8 *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1 (1979).*

n9 *Id. at 20* (noting that the Court of Appeals and CBS recognized that "costs are prohibitive for licenses with individual radio stations, nightclubs, and restaurants .... ").

nl0 A "decisive number" refers to any number that the joint venture settles on as necessary for making a certain rule. This could be a majority of members, or perhaps a supermajority such as two-thirds; it could also be a majority of voting shares where venture partners have unequal interests; or perhaps even a supermajority of shares. In some cases a venture might make decisions only by unanimous consent. In that case a "decisive number" can be one. See, for example, *Associated Press v. United States, 326 U.S. 1 (1945),* where under the original rule, a single newspaper in the same town as an applicant for new membership could veto the application. See the lower court opinion, *52 F. Supp. at 364,* and infra text accompanying notes 95-120.

n11 See infra text accompanying notes 168-182.

n12 *Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492 (1988).* See infra text accompanying notes 169-71.

n13 See *Hartford Fire Ins. Co. v. California, 113 S. Ct. 2891 (1993).* See infra text accompanying notes 63-70.

n14 *Allied Tube, 486 U.S. 492.*

n15 See *SCFC ILC, Inc. v. VISA U.S.A., Inc., 819 F. Supp. 956 (D. Utah 1993),* rev'd, *36 F.3d 958 (lOth Cir. 1994).*

n16 In VISA, the Tenth Circuit concluded, erroneously, that a firm could not challenge joint venture exclusion unless the defendants excluded the plaintiff from the market altogether. See supra text accompanying note 15 and infra text accompanying notes 150-58.

n17 For example, the blanket licensing arrangement in the Broadcast Music decision (1) admitted all holders of performance rights that wished to be included; and (2) permitted any such holder to sell unlimited licenses outside the context of the blanket license arrangement. Under such rules, and with several thousand members, collusion is impossible. *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1 (1979).*

n18 For example, *Associated Press v. United States, 326 U.S. 1 (1945)* (member exclusion), came very close to applying such a rule. See infra text accompanying notes 32, 95-120. The record with respect to product exclusion is very much the same. See, e.g., *Radiant Burners, Inc. v. Peoples Gas Light & Coke Co., 364 U.S. 656 (1961)* (applying essentially per se analysis, although "per se" label not used, to exclusion of plaintiffs gas heater from venture approval).

n19 E.g., Donald I. Baker, Compulsory Access to Network Joint Ventures Under the Sherman Act: Rules or Roulette, *4 Utah L Rev. 999 (1993).* See also William J. Baumol & Janusz A. Ordover, Antitrust: Source of Dynamic and Static Inefficiencies?, in Antitrust, Innovation, and Competitiveness 82 (Thomas M. Jorde & David J. Teece, eds. 1992); Grossman & Shapiro, supra note 5. However, not all economists agree that antitrust has interfered substantially with the ability of joint ventures to achieve available efficiencies. See, e.g., *Shapiro & Willig, supra* note 5, at 119-124 (noting that there is no evidence that antitrust policy stifles efficiency enhancing joint ventures); Joel B. Eisen, Antitrust Reform for Joint Production Ventures, *30 Jurimetrics J. 253, 261 (1990)* (noting that antitrust "not a large barrier" to formation of joint ventures). See also George L. Priest, Cartels and Patent License Arrangements, *20* J.L & *Econ. 309 (1977)* (developing methodologies for distinguishing efficient from inefficient arrangements on the basis of whether compensation goes from the patentee to the

joint licensees, or vice-versa); for example, if the called-for royalties are trivial, then the patent licensing arrangement is very likely a front for collusion. But cf., *United States v. General Electric, 272 U.S. 476 (1926)* (holding that patentee was entitled to restrict its licensee's prices).

n20 On the difference between joint ventures and mergers, see Hovenkamp, supra note 1, section 5.2d.

n21 See discussion infra, text accompanying notes 149-81. See also *Chicago Professional Sports Limited Partnership & WGN v. Nat'l Basketball Ass'n, 961 F.2d 667* (7th Cir.) (noting that a sports league operated as a joint venture in the organization of games, but more like a cartel in the sale of its output), cert. denied, *113 S. Ct. 409 (1992).*

n22 See, e.g., Baker, supra note 19; Dennis W. Carlton & J. Mark Klamer, The Need For Coordination Among Firms, With Special Reference to Network Industries, *50 U. Chi. L Rev. 446 (1983);* Hovenkamp, supra note 1, at section 5.6c.

n23 See, e.g., Request for Comments on Draft Antitrust Guidelines for the Licensing and Acquisition of Intellectual Property, section 2.3, *59 Fed. Reg. 41,339, 41,340-41 (1994)* [hereinafter Intellectual Property Guidelines] (noting that restrictive licenses may be necessary to control free riding).

n24 See, e.g., Baker, supra note 19, at 1006 (defining a network joint venture as a combination of facilities and rules leading to exchanges of traffic and information).

n25 Such networks permit multiple banks to share ATM machines, and customers to withdraw or deposit monies through a machine managed by a bank other than the one in which they have an account. See William

Blumenthal, Three Vexing Issues under the Essential Facilities Doctrine: ATM Networks as Illustration, *58 Antitrust* LJ. *855 (1990).*

n26 See *NCAA v. Bd. of Regents of the Univ. of Oklahoma, 468 U.S. 85 (1984).*

n27 United States v. AT&T, 552 F. Supp. 131 (D.D.C. 1982), aff'd mem. sub nom., *Maryland v. United States, 460 U.S. 1001 (1983).*

n28 See Michael K. Kellogg et al., Federal Telecommunications Law 591-599 (1992).

n29 See infra text accompanying notes 151-59.

n30 For example, see *In re General Motors Corp., 103 F.T.C. 374, 388 (1984),* approving GM/Toyota production joint venture, subject to certain restrictions, where one effect would be to teach an American automobile manufacturer about Japanese production methods thought to be highly efficient. Two Commissioners dissented. One believed that the Commission exaggerated the learning potential and understated the potential for collusion. *Id. at 391* (Pertschuk, Commissioner, dissenting); the other believed that efficiencies, even if proven, should not be taken into account, and that the dangers of anticompetitive information exchanges were substantial. *Id. at 391-92* (Bailey, Commissioner, dissenting).

n31 See *United States v. Terminal R.R. Ass'n, 224 U.S. 383 (1912).* See infra text accompanying notes 81-94.

n32 See *Associated Press v. United States, 326 U.S. 1 (1945).* See infra text accompanying notes 95-120.

n33 See *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1 (1979).*

n34 *United States v. Trans-Missouri Freight Ass'n, 166 U.S. 290 (1897).*

n35 *United States v. Terminal R.R. Ass'n, 224 U.S. 383 (1912).*

n36 See Isaiah L. Sharfman, The Interstate Commerce Commission: A Study in Administrative Law and Procedure (2 vols. 1931); Gabriel Kolko, Railroads and Regulation, 1877-1916 35-70 (1965); Herbert Hovenkamp, Regulatory Conflict in the Gilded Age: Federalism and the Railroad Problem, *97 Yale l-,J. 1017 (1988).*

n37 See Kellogg et al., supra note 28, at 602-610.

n38 See Hovenkamp, supra note 1, sections 19.1-19.2.

n39 See R. H. Coase, The Nature of the Firm, 4 Economica (n.s.) 386 (1937); R. H. Coase, The Firm, the Market, and the Law (1988); The Nature of the Firm: Origins, Evolution, and Development (Oliver E. Williamson & S. Winter, eds. 1991); Herbert Hovenkamp, Market Efficiency and the Domain of the Firm, *18 J. Corp. L 173 (1993).*

n40 Coase, supra note 39; Oliver E. Williamson, Markets and Hierarchies: Analysis and Antitrust Implications (1975); Oliver E. Williamson, Economic Institutions of Capitalism: Firms, Markets, Relational Contracting (1982).

n41 See Oliver E. Williamson, Transaction-Cost Economics: the Governance of Contractual Relations, *22 J.L. & Econ. 233 (1979).* Indeed, the joint venture is a strong example of "neoclassical" contracting, in which the firms make longterm, open ended commitments that provide opportunities for future exercises of discretion. See Ian

MacNeil, Contracts: Adjustment of Long-Term Economic Relations Under Classical, Neoclassical, and Relational Contract Law, *72 Nw. U. L. Rev. 854 (1978).*

n42 *35 U.S.C. sections* 1-376 (1988).

n43 See Louis Kaplow, The Patent-Antitrust Intersection: A Reappraisal, *97 Harv. L. Rev. 1813 (1984).*

n44 That is, impairments that result from the cartel-like structure of the venture and not merely from the venture's anticipated patent or other intellectual property rights.

n45 That is, at least one person is better off and no one is worse off. To be sure, the addition of aluminum to the market in the illustration represents a pure Pareto improvement only if the remaining steel manufacturers are indifferent to the addition of aluminum, which cannot be presumed. However, they would be indifferent if (1) they had no fixed costs and were earning no economic profits, so they were indifferent to the loss of volume; or (2) they were compensated by the aluminum producer.

In any case, however, the addition of aluminum is a welfare improvement under the so-called potential Pareto criterion. Under this criterion, sometimes called Kaldor-Hicks efficiency, a move is efficient if the gains gain enough to compensate the losers so that the losers become indifferent. Thus, the illustration shows that perfect competition is not Kaldor-Hicks efficient if the model is permitted to take changes such as product innovation into account.

n46 E.g., Kenneth J.Arrow & Frank H. Hahn, General Competitive Analysis (1971).

n47 See Joseph A. Schumpeter, Capitalism, Socialism and Democracy (1942). On the development of the theory, see Richard Swedberg, Schumpeter: A Biography 136-166 (1991).

n48 Schumpeter, supra note 47, at 88, 103.

n49 Id. at ch. 8.

n50 A sampling of recent literature as well as classics: Kevin Arquit & Joseph Kattan, Efficiency Considerations and Horizontal Restraints, *36 Antitrust Bull 717, 722 (1991);* Michael L. Katz & Janusz A. Ordover, R&D Cooperation and Competition, in Brookings Papers on Economic Activity 137, 142 (Martin Neil Baily & Clifford Winston eds., 1990); Janusz A. Ordover & William Baumol, Antitrust Policy and High-Technology Industries, 4 Oxford Rev. Econ. Policy 13, 14 (1988); William L. Baldwin & John T. Scott, Market Structure and Technological Change (1987); Frederick. M. Scherer, Innovation and Growth: Schumpeterian Perspectives (1984); Partha Dasgupta, The Theory of Technological Competition, in New Developments in the Analysis of Market Structure 399 (Joseph E. Stiglitz & Frank Mathewson eds. 1986); Morton Kamien & Nancy Schwartz, Market Structure and Innovation 14-15 (1982); Robert Solow, Technical Change and the Aggregate Production Function, 39 Rev. Econ. & Stat. 312 (1957) (arguing that great majority of growth came from innovation).

n51 See, e.g., Harvey Leibenstein, Allocative Efficiency vs. X-Efficiency, *56 Am. Econ. Rev. 392 (1966);* John J. Siegfried & Edwin H. Wheeler, Cost Efficiency and Monopoly Power: A Survey, 21 Q. Rev. Econ. & Bus. 25 (1981).

n52 On this point, see Frederick M. Scherer & David Ross, Industrial Market Structure and Economic Performance 662-685 (3d ed. 1990).

n53 E.g., Baumol & Ordover, supra note 19. See also Thomas M. Jorde & David J. Teece, Rule of Reason Analysis of

Horizontal Arrangements: Agreements Designed to Advance Innovation and Commercialize Technology, *61 Antitrust L.J. 579, 599-600 (1993).*

n54 See Richard J. Gilbert & David M. G. Newbery, Preemptive Patenting and the Persistence of Monopoly, *72 Am. Econ. Rev. 514 (1982)* (monopolist's selection of patented technology); Oliver E. Williamson, Wage Rates as a Barrier to Entry: the Pennington Case in Perspective, 82 Q. J. Econ. 85 (1968) (selection of labor vs. capital intensive technology).

n55 *E.g,,Allied Tube & Conduit Corp. v. Indian Head, 486 U.S. 492 (1988); SCFC ILC, Inc. v. VISA U.S.A., Inc.; 819 F. Supp. 956 (D.Utah 1993),* rev'd, *36 F.3d 958 (lOth Or. 1994).* See infra text accompanying notes 62-67, 151-85.

n56 See the discussion in Jean Tirole, The Theory of Industrial Organization 401-404 (1988). Others making the same suggestion include Joseph Kattan, Antitrust Analysis of Technology Joint Ventures: Allocative Efficiency and the Rewards of Innovation, *61 Antitrust* LJ. *937 (1993);* Janusz A. Ordover & Robert D. Willig, Antitrust for High-Technology Industries: Assessing Research Joint Ventures and Mergers, *28 J.L. & Econ. 311 (1985).* See generally Eric von Hippel, The Sources of Innovation 47-55 (1988).

n57 See Intellectual Property Guidelines, supra note 23, section 3.2.3 (speaking of agreements to restrict innovation); id. section 5.6 (relating to grantback agreements that may retard innovation).

n58 E.g., *SCFC ILC, Inc. v. VISA U.S.A., Inc., 36 F.3d 958 (lOth Cir. 1994)* (inferring from the fact that individual Visa members behaved competitively toward each other that a jointly agreed to exclusion rule could not harm competition).

n59 The profitability of excluding aluminum does not depend on the existence of a steel cartel earning monopoly profits. Even if the steel producers were behaving competitively and earning only competitive returns on their investments, they would still be better off to exclude aluminum from the market if they thought significant numbers of customers would switch from steel to aluminum. The effect of the switch would be to reduce demand for steel below the current level. As a result, each firm would earn even less on its investment, and some firms might even have to leave the market.

[SEE FIGURE IN ORIGINAL]

Figure 1 illustrates the impact of a downward demand shift on the market as a whole. Downward-sloping demand curve D is the demand for steel before aluminum is introduced, while D' is the reduced demand for steel after aluminum appears on the market. As a result, the output of steel is reduced from Q to Q', entailing either that firms reduce their output or that at least one firm exits from the market. If the supply curve for steel is upward sloping, as in the figure, the price will also drop from P to P'. Even a competitive firm would hardly be indifferent to these losses.

[SEE FIGURE IN ORIGINAL]

Figure 2 illustrates the impact of a downward demand shift on a single competitive firm. Horizontal demand curve D shows demand facing the individual firm before the introduction of aluminum, and D' shows demand

after aluminum appears on the market. The firm will reduce its output from Q to Q', and its price will drop from P to P'. Whether the firm continues to earn a profit at the lower price depends on its average total costs. But if the average total cost curve bottoms out between D and D', as in the figure, the introduction of aluminum would move the firm from profits to losses.

n60 On the two forms of exclusion, see infra text accompanying notes 168-82.

n61 *American Society of Mechanical Engineers v. Hydrolevel Corp., 456 U.S. 556 (1982)* (affirming judgment on a jury verdict for the plaintiff).

n62 *Allied Tube & Conduit Corp. v. Indian Head, 486 U.S. 492 (1988).* See also United States v. Motor Vehicle Mfrs. Ass'n, Inc., 1979-1 Trade Cas. paragraph 62,557 (C.D.Cal. 1979) (barring (through a consent decree) cooperative efforts to delay and obstruct development of automobile pollution control devices).

n63 *Hartford Fire Ins. Co. v. California, 113 S. Ct. 2891 (1993).*

n64 Conduit is a hard, impact and weather resistant tube through which electric wires are run in installations where the wire might be subjected to weather or other adverse conditions.

n65 See the lower court's opinion, *817 F.2d at 945.*

n66 See *Allied Tube, 486 U.S. at 496.* There was some concern, however, that during fires the PVC conduit would emit toxic fumes.

n67 *Id. at 497-498.* The plastic conduit was eventually approved in 1984. Today it enjoys widespread use as an alternative to steel conduit.

n68 *Hartford Fire Ins. Co. v. California, 113 S. Ct. 2891 (1993).*

n69 *Id. at 2896-2897* (most ISO members could not afford to write a certain kind of coverage if ISO withdrew its support services for that coverage).

n70 See *id. at 2896.*

n71 See infra text accompanying notes 149-81.

n72 But see John Hilke & Philip Nelson, Antitrust Policy and the Market Concentration Doctrine: A Response, J. Bus. Econ. 17 (1981) (arguing that antitrust focuses on dynamic concerns).

n73 *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1, 19-20 (1979).*

n74 See supra text accompanying notes 41-60 and infra text accompanying notes 217-28.

n75 *United States v. Terminal R.R. Ass'n, 224 U.S. 383 (1912).*

n76 *United States v. Trans-Missouri Freight Ass'n, 166 U.S. 290 (1897).* On the economics of railroad operations during this era, see Hovenkamp, supra note 6.

n77 *United States v. Trans-Missouri Freight Ass'n, 58 F. 58, 79-80 (8th Cir. 1893),* rev'd, *166 U.S. 290 (1897).*

n78 As a result, the Interstate Commerce Commission approved of various joint running agreements

such as the *Trans-Missouri Freight Association. See 12 ICCAnn. Rep. 10-16 (1898);* Hovenkamp, supra note 6, at chs. 12, 13. The illustrious judge, legal scholar, and then Chairman of the ICC, Thomas M. Cooley, wrote:

> It is the refusal to join with other roads in making rates, or the demand of an unreasonable share of a joint rate when one is made;.., it is the refusal to unite in through bills of lading at agreed rates, or to receive for transportation of persons the tickets that have been given by other roads .... The evils in railroad service nearly all find their origins here. •.. If a rate-sheet [referring to published tariffs of freight charges that the railroads promulgated] affected only the road itself and its customers, [the setting of rates] would in a great many cases be of local importance only and other roads not directly competing with the road making it need not concern themselves specially with its being put in force• But so inextricably are the railroads of the country intermingled in interest; in so many ways do they form routes from business center to business center; from the lakes to the gulf and from ocean to ocean; so easy is it for almost any seemingly unimportant road to be made a part of some direct or indirect route which shall constitute a great channel of commerce; that any considerable change in the rate-sheets by any one of these five hundred boards is not only likely to affect the business and the ratesheets of the roads which are its immediate rivals, but to reach out also in its influence from road to road in all directions ....
>
> *5 ICCAnn. Rep. 330-332 (1891).*

See also *12 ICCAnn. Rep. 13 (1898)* (expressing approval of agreements that cover "the formation of through lines, the interchange of business, the use of cars, the keeping of mutual accounts, the making of uniform classifications, the establishment of whatever rules may be necessary for the handing of railway traffic.., which are not believed to be in any way obnoxious to the antitrust law.").

n79 See *Cincinnati, New Orleans & Tex. Pac. Rwy. Co. v. I.C.C., 162 U.S. 184 (1896)* (noting that Commission lacked power to set rates initially, but only to correct unjust or discriminatory rates).

n80 Of similar effect is *United States v. Joint-Traffic Ass'n, 171 U.S. 505 (1898).*

n81 *United States v. Terminal R.R. Ass'n, 224 U.S. 383 (1912).*

n82 E.g., Phillip Areeda, Essential Facilities: An Epithet in Need of Limiting Principles, *58 Antitrust* L.J. *841 (1990);* Daniel Troy, Unclogging the Bottleneck: A New Essential Facilities Doctrine, *83 Colum. h Rev. 441 (1983);* David Gerger, Rethinking the Monopolist's Duty to Deal: A Legal and Economic Critique of the Doctrine of Essential Facilities, *74 Va. L. Rev. 1609 (1988);* Gregory Werden, The Law and Economics of the Essential Facilities Doctrine, 32 St. Louis U. L.J. (1988); James Ratner, Should There be an Essential Facilities Doctrine? *21 U.C. Davis L Rev. 327 (1988).* See also David Reiffen & Andrew N. Kleit, Terminal Railroad Revisited: Foreclosure of an Essential Facility or Simple Horizontal Monopoly, *33* J.L & *Econ. 419, 434-437 (1990).*

n83 In an earlier state court decision, the court had refused to break up the Association under state corporate law. *State v. Terminal Ass'n of St. Louis, 182 Mo. 284, 81 S.W. 395 (1904).*

n84 "It is, as a practical matter, impossible for any railroad company to pass through, or even enter St. Louis, so as to be within reach of its industries or commerce, without using the facilities entirely controlled by the terminal company." *Terminal R.R., 224 U.S at 397.*

n85 *Id. at 400.* "That other companies are permitted to use the facilities of the terminal company upon paying the same charges paid by the proprietary companies seems to be conceded." Id.

n86 Counsel for the defendant averred that any railroad who requested an ownership interest would have been given one, but the Court went by the corporate charter, which required unanimous consent. *Id. at 400.* "We fail to find in either of the contracts referred to any provision abrogating the requirement of unanimous consent to the admission of other companies to the ownership of the terminal company, though counsel say that no such company will now find itself excluded from joint use or ownership upon application."

n87 See *Munn v. Illinois, 94 U.S. 113 (1877)* (permitting price regulation of unincorporated grain elevator acknowledged to be bottleneck); *Buddv. New York, 143 U.S. 517 (1892)* (permitting price regulation of grain elevator acknowledged to be monopoly).

n88 On this point, see David Reiffen & Andrew N. Kleit, Terminal Railroad Revisited: Foreclosure of an Essential Facility or Simple Horizontal Monopoly, *33 J.L. & Econ. 419, 434-437 (1990).*

n89 *Terminal R.R., 224 U.S. at 411.*

n90 On the administration of compulsory access decrees, see infra Part IX.

n91 *United States v. Terminal R.R. Ass'n, 224 U.S. 383, 411.*

n92 Baker, supra note 19, at 1025.

n93 *Terminal R.R., 224 U.S. at 407-409.*

n94 *Id. at 407.*

n95 *Associated Press v. United States, 326 U.S. 1 (1945).*

n96 See the district court's opinion, *United States v. Associated Press, 52 F. Supp. 362, 364 (1943).*

n97 *Associated Press, 326 U.S. at 4.*

n98 See the lower court opinion, *52 F. Supp. at 364.*

n99. Id.

n100. Id.

n101 Under the rules, if a newspaper from any town applied for AP membership, it was required to pay an entry fee equal to ten percent of the accumulated assessments that had been paid by all other competing newspapers in the same town since 1900. *Id. at 365.*

n102 Perhaps the most distinguished three judge panel ever assembled: Learned Hand, Augustus Hand, and Leonard Swan.

n103 With Judge Swan dissenting.

n104 See *Bd. of Trade of City of Chicago v. United States*, 246 U.S. 231 (1918). Under that decision, which contains the historically most important formulation of the rule of reason, virtually everything is relevant. As Justice Brandeis said:

The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable.

Id. at 238. For a critique of the "test's" overbreadth and lack of focus, see Hovenkamp, supra note 1, section 5.6b.

n105

That industry [i.e., newspapers] serves one of the most vital of all general interests: the dissemination of news from as many different sources, and with as many different facets and colors as is possible. That interest is closely akin to, if indeed not the same as, the interest protected by the First Amendment; it presupposes that right conclusions are more likely to be gathered out of a multitude of tongues, than through any kind of authoritative selection.

52 F. Supp. at 372.

n106 The exceptions are the small number of newspapers with a national circulation, including the New York Times, Wall Street Journal, Christian Science Monitor, and USA Today.

n107 The degree of cost savings results from the fact that news stories are intellectual property. Common to such property is the fact that fixed costs are an unusually large portion of the cost of the entire product. That is to say, the cost of sending the reporter to cover the inauguration might be substantial. But once the story is written, it can be photocopied, wired, or repeated an infinite number of times at very little incremental cost. In that case, the more newspapers who share the story, the lower the cost per newspaper.

Most manufactured products do not enjoy scale economies of this magnitude. As a result, the savings from joint production are not nearly as large. For example, an automobile plant might have a capacity of 50,000 cars annually. Joint production, such as by GM and Toyota, would produce cost savings up to the point that 50,000 cars were produced, but from that point it would actually cost more to produce additional cars out of the same plant and the venture would have reached its optimal capacity.

n108 *See52F. Supp. at366.*

n109 E.g., Baker, supra note 19, at 1035.

n110 *52F. Supp. at366. However, therewerealso* 20-30much smaller agencies providing various forms ofwire service, *ld. at 368.*

nl 11 See *52 F. Supp. at 366-368.*

n112 See Baker, supra note 19, at 1069.

n113 See generally *52 F. Supp. at 366* (deeming UP and INS to be the only two wire services comparable to AP in terms of size and efficiency).

n114 See generally *52 F.Supp. at 366-367, 371-372. AP*

newspapers accounted for 96% of morning circulation, while LIP accounted for 64%. AP accounted for 77% of total evening circulation, while UP had 65%. The AP staff was larger than the staffs of UP and INS together. AP had more than 250 offices in the United States and abroad, while the other two had about 135. AP's annual operating budget was about $12,000,000. UP's budget was $7,000,000 and INS' budget was $2,600,000. Id.

n115 See Gregory Gordon & Ronald D. Cohen, Down to the Wire: UPI's Fight for Survival 17 (1990).

n116 Id. at 20.

n117 See Baker, supra note 19, at 1071.

n118 However, product differentiation permits multiple firms to survive notwithstanding substantial scale economies. For example, in addition to UPI is Reuters, a successful wire service that services many newspapers, particularly those that are relatively sophisticated in the reporting of political and business news.

nl19 E.g., Baker, supra note 19, at 1068-1074.

n120 That is to say, all the economies that accrue to AP with respect to the first story about the President's inauguration also accrue to it for the second and subsequent stories.

n121 *Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 589590 (1985).* Some facts are from the lower court opinion. *738 F.2d 1509.*

n122 Whether this fact made Aspen a relevant market capable of being monopolized is dubious, but the market power issue was not before the Court. See Phillip E.

Areeda & Herbert Hovenkamp, Antitrust Law paragraph 518. l h (1994 Supp.).

n123 This very condensed statement of facts ignores that there were originally three firms and that various ticket combinations preceded the joint venture at issue.

n124 Id. at 590.

n125 Id. at 592.

n126 Id.

n127 Id. at 592. In fact, Ski Company's best multi-mountain ticket, which covered all three of its own mountains, sold fewer than half as many as the allAspen four-mountain ticket.

n128 See, e.g., Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law paragraph 736.1 (1994 Supp.).

n129 E.g., *Olympia Equip. Leasing v. Western Union Tel. Co., 797 F.2d 370 (7th Cir. 1986)* (finding that a firm retiring equipment and exiting from a market had no duty to cooperate with rival selling agent), cert. denied, *480 U.S. 934 (1987).* Other cases are collected in Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law paragraph 736.2 (1994 Supp.).

n130 That is to say, the cost to the ski company imposed by any skier relates to the number of times the skier uses the lift, slopes and other facilities needing maintenance or attention. A skier who has a four-mountain ticket cannot make any more trips up the ski lift and down the mountain than a skier who has a ticket covering a single mountain; she simply makes the trips up different lifts and down different slopes. Indeed, the skier with a four-

mountain ticket may actually make fewer trips per day because of the time involved in moving from one mountain to another.

n131 See supra note 130 (suggesting that the costs of giving a four-mountain ticket were no larger than the costs of a three-mountain ticket).

n132 The Coase Theorem suggests that, absent transaction costs, the parties would have continued to participate in the venture by settling on a mutually advantageous division of the profits. Ronald Coase, The Problem of Social Cost, 3 J.L. *& Econ. 1 (1960).*

n133 For example, a shoe store that sold shoes in pairs would surely have a market share more than twice as large as a shoe store precisely half the size that sold only left shoes.

n134 Since the litigation Skiing Co. & Highlands have merged. The new firm, which now controls all four mountains, also continues to offer a four-mountain ticket. Promotional Brochure, Aspen Skiing Co., 1994-1995 [on file with author].

n135 *SCFC ILC, Inc. v. VISA U.S.A., Inc., 819 F. Supp. 956 (D.Utah 1993),* rev'd, *36 F.3d 958 (lOth Cir. 1994). See* infra Part IV.B.-C.

n136 *Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585 (1985).* See supra Part III.C.

n137 *United States v. Terminal R.R. Ass'n, 224 U.S. 383 (1912).* See supra Part III.A.

n138 *Associated Press v. United States, 326 U.S. 1 (1945).* See supra Part III.B.

n139 *SCFC ILC, Inc. v. VISA U.S.A., Inc., 819 F. Supp. 956 (D. Utah 1993),* rev'd, *36 F.3d 958 (lOth Cir. 1994).*

n140 But even where the excluded firm is already a member, as in the case of product exclusion, individual members maximize their individual profits, not necessarily those of the venture. See supra text accompanying notes 62-67.

n141 See infra Part VI.B.

n142 This was the outcome of the Aspen Skiing plaintiffs insistence that revenues under the venture be divided in proportion to actual use. See the discussion *of Aspen Skiing supra* text accompanying notes 120-34.

n143 If they could be, the venture could always charge subsequent joiners an entry fee designed to compensate founding members for their risk.

n144 See infra part VI.A.

n145 Of course, many joint ventures, such as research joint ventures, are intermediaries rather than final output sellers: they supply inputs to the member firms. But even these joint ventures can be viewed as sellers of the venture's output to the participating firms.

n146 See, e.g., 6 Phillip E. Areeda, Antitrust Law paragraph 1402 (1986); Hovenkamp, supra note 1, at ch. 6.

n147 E.g., *Timken Roller Bearing Co. v. United States, 341 U.S. 593 (1951)* (condemning joint venture among farms united by common ownership); *United States v. Topco Associates, Inc., 405 U.S. 596 (1972)* (striking down under per se rule horizontal territorial division among joint venturers who lacked substantial market share in any territory).

n148 E.g., *United States v. Trans-Missouri Freight Ass'n, 166 U.S. 290 (1897).* See supra Part III.A. See also *United States v. Penn-Olin Chem. Co., 378 U.S. 158 (1964)* (applying an overly aggressive potential competition theory to strike down a joint venture); *Topco, 405 U.S. 596.*

n149 E.g., George J. Stigler, The Theory of Price (3d ed. 1966).

n150 See Hovenkamp, supra note 1, section 4.1.

n151 *SCFC ILC, Inc. v. VISA U.S.A., Inc., 819 F. Supp. 956 (D. Utah 1993), 36 F.3d 958 (lOth Cir. 1994).* At the time the litigation commenced, Dean Witter was owned by Sears. For an economic analysis of the credit card network, focusing on Visa, see Dennis W. Carlton & Alan S. Frankel, The Antitrust Economics of Credit Card Networks, *63 Antitrust* L.J. *643 (1995).*

n152 Board members were elected by region, but any member with more than 10% of total outstanding VISA cards received automatic membership on the board. *819 F. Supp. at 962.*

n153 *Id, at962.*

n154 We say "presumptively" because the possibility of free riding has not yet been considered. See infra Part VI.A.

n155 Bylaw section 2.06 states: "The corporation shall not accept for membership any applicant which is issuing, directly or indirectly, Discover Cards or American Express cards, or any other cards deemed competitive .... "*819 F. Supp. at 964.* Under the bylaw, non-VISA members "who develop a successful proprietary card would be prohibited from joining the VISA system and current VISA members would be expelled from the system if they developed such a card." *Id. at 966.*

n156 Initially, VISA excluded MasterCard members, but changed its mind in response to *Worthen Bank & Trust Co. v. Nat'l Bankamericard, Inc., 345 F. Supp. 1309 (E.D. Ark. 1972),* rev'd, *485 F.2d 119 (8th Cir.1973),* cert. denied, *415 U.S. 918 (1974),* and a Justice Department opinion seeing no objection to the duality. See *819 F. Supp. at 962.* Further, Diners' Club and Carte Blanche had been grandparented in; banks who issued those cards were also permitted to issue a VISA card.

n157 *819 F. Supp. at 963.*

n158 See *id. at 987 and n.33.* Dean Witter's proposed "Prime Option" VISA contemplated a 25-day grace period for all card holders, thus permitting them to pay their full bill during this period with no interest charge whatsoever. In addition, Dean Witter proposed a low 9.9% rate of interest on the current and the previous month's purchases, and a higher rate of 9.9% plus the Prime Rate on older purchases -- this in contrast to the more general practice of charging the higher rate for all balances not paid within the grace period. Finally, the proposed VISA card carried no annual fee, a provision entitling card holder to skip a payment periodically without impairing their credit standing, and a standard opening credit limit of $3500. Id.

n159 On the relevance of market power and the methods for measuring it, see infra Part V.

n160 For example, if the new entry or new product is Kaldor-Hicks efficient, the new entrant's gains will be large enough so that it can compensate all losers and still have some gains left over. See Richard A. Posner, Economic Analysis of Law 13-16 (4th ed. 1992).

n161 See discussion supra, text accompanying notes 62-67; see also *Consolidated Metal Products, Inc. v. American Petroleum Institute, 846 F.2d 284 (5th Cir. 1988); United States v. Realty Multi-List, Inc, 629 F.2d 1351 (5th Cir. 1980).* In the case of the real estate multiple-listing service, the more real estate agents engaged in the joint activity of showing a particular house, the more likely a sale and resulting commission. But if the new applicant is a low cost commission cutter, a disproportionately high percentage of new listings would go to it, thus depriving existing members of market share.

n162 In the most typical venture arrangements voting rights are given one to each member, or the members elect a board of directors who votes on all important decisions. Alternatively, venture members may have voting rights in proportion to their ownership interests. For example, if the venture is incorporated and the venturers own shares, they may have one vote per share. See Steven R. Salbu & Richard A. Brahm, Strategic Considerations in Designing Joint Venture Contracts, *1992 Colum. Bus. L Rev. 253 (1992).*

n163 As a general matter, it cannot be shown that individual voting by members of an organization will yield outcomes that can be said to maximize the welfare of the organization as a whole. See Kenneth J. Arrow, Social Choice and Individual Value (2d ed. 1963); Amartya Sen, Choice, Welfare and Measurement 14-15, 142-48 (1982). For

explorations of the meaning and domain of Arrow's Theorem, see Herbert Hovenkamp, Rationality in Law & Economics, *60 Geo. Wash. L Rev. 293 (1992);* Herbert Hovenkamp, Arrow's Theorem: Ordinalism and Republican Government, *75 Iowa L Rev. 949 (1990).*

One can imagine an alternative decision making regime in which venture members bid for the right to innovate within the venture. For example, if Indian Head bid more for the right to introduce its plastic conduit than the steel producers bid for the right to be free of plastic conduit's competition, then plastic conduit would be introduced. In a perfectly functioning market, plastic conduit would win the bid only if venture wide gains exceeded losses. But such a bidding scheme probably does not exist, certainly cannot be assumed, and would certainly be imperfect if it did exist.

n164 Once again, in a zero transaction cost world, the prospective member might be able to pay existing members an entry fee sufficient to cover their anticipated losses. If Dean Witter's entry were efficient, its gains would at least sometimes exceed the losses of existing VISA members, so such a payment would be possible. But when market information is imperfect and transaction costs are high, such payments are unlikely to occur. Further, if the effect of Dean Witter's entry into VISA is to eliminate any collusion or other supracompetitive pricing resulting from other market imperfections occurring in the VISA market, Dean Witter's gains might not be large enough to compensate existing members for their losses, even though its entry is efficient. The remaining gains will accrue to consumers.

But under the AP membership rules, if a newspaper from any town applied for AP membership, it was required to pay an entry fee equal to ten percent of the accumulated

assessments that had been paid by all other competing newspapers in the same town since 1900. See supra note 101. This was almost certainly a transfer payment intended to compensate existing competitor-members for the losses resulting from increased competition that the efficient entry of a competing newspaper would produce.

n165 See generally Benjamin Klein, Vertical Integration as Organization Ownership, 4 J.L. Econ. & Org. 199 (1988); Paul H. Rubin, The Theory of the Firm and the Structure of the Franchise Contract, *21 J.L. & Econ. 223 (1978);* Roger D. Blair & David L. Kaserman, Vertical Integration, Tying, and Alternative Vertical Control Mechanisms, *20 Conn. L. Rev. 523, 529-530, 538-540 (1988).*

n166 See *Williamson, Markets and Hierarchies, supra* note 40.

n167 This explains why state statutes permitting one franchisee to veto the franchisor's decision to create a second franchise close by are generally inefficient, as are state laws restricting franchise terminations. See Frederick H. Dark & Michael S. Weisbach, The Economic Effects of Franchise Termination Laws, *34 J.L. & Econ. 101 (1991);* Thomas M. Pitegoff, Franchise Relationship Laws: A Minefield for Franchisors, 45 Bus. L. 289 (1989); see also J.H. Beales III& T. Muris, The Foundations of Franchise Regulation: Issues and Evidence (George Mason Univ. Law and Economics Working Paper #94-006, 1994).

n168 E.g., *Eliason Corp. v. Nat'l Sanitation Foundation, 614 F.2d 126 (6th* Cir.) (applying rule of reason and upholding standards applied by testing organization), cert. denied, *449 U.S. 826 (1980); Moore v. Boating Indus. Ass'n, 819 F.2d 693* (7th Cir.), cert. denied, *484 U.S. 854 (1987); Sessions Tank Liners, Inc. v. Joor Mfg., 827 F.2d 458 (9th Cir. 1987),* vacated, *487 U.S. 1213 (1988),* on remand, *852 F.2d 484 (9th Cir. 1988).*

n169 See supra text accompanying notes 62-67.

n170 That is, if economies of scale exist and the plants are currently running at capacity, a substantial demand reduction would entail higher costs. See supra text and figures accompanying note 59.

n171 See supra text and figures accompanying notes 59.

n172 *Hartford Fire Ins. Co. v. California, 113 S. Ct. 2891 (1913).* For additional facts, see supra text accompanying notes 68-70.

n173 See *Hartford Fire Insurance, 113 S. Ct. at 2897.* "ISO also supplies actuarial and rating information: it collects, aggregates, interprets, and distributes data on the premiums charged, claims filed and paid, and defense costs expended with respect to each form .... " Id.

n174 See supra text accompanying notes 69-70.

n175 They also allegedly did a third thing that is not relevant here: they got reinsurers such as Lloyds of London to stop writing reinsurance on the broader forms of coverage. Reinsurance is insurance for insurers, which effectively permits them to reduce their own risk exposure. See *113 S. Ct. at 2909, n.23.*

n176 *United States v. Terminal R.R. Ass'n, 224 U.S. 383 (1912);* see supra Part III.A.

n177 *Associated Press v. United States, 326 U.S. 1 (1945).* See supra Part III.B.

n178 *SCFC ILC, Inc. v. VISA U.S.A., Inc., 819 F. Supp. 956 (D. Utah 1993),* rev'd, *36 F.3d 958 (lOth Cir. 1994);* see supra discussion in Part IV.B.-C.

n179 E.g., *Northwest Wholesale Stationers v. Pacific Stationery & Printing Co., 472 U.S. 284 (1985).* See infra discussion in Part V.A.

n180 In the traditional, or cooperative, cartel, the cartel's optimal aggregate output remains the same -- i.e., the monopoly output -- regardless of the number of members; so monopoly profits would simply have to be shared among more firms. In the ease of non-cooperative oligopoly behavior, the price would decline as additional firms entered. See Hovenkamp, supra note 1, section 4.1.

n181 *SCFC ILC, Inc. v. VISA U.S.A., Inc., 819 F. Supp. 956 (D.Utah 1993),* rev'd, *36 F.3d 958 (lOth Cir. 1994). See* supra text accompanying notes 154-57.

n182 See supra text accompanying note 181.

n183 See 2 Phillip Areeda & Herbert Hovenkamp, Antitrust Law paragraph 373d (rev. ed. 1995).

n184 *SCFC ILC, Inc. v. VISA U.S.A., Inc., 36 F.3d 958, 967-69 (lOth Cir. 1994).* In many private actions challenging joint venture exclusion, the plaintiff remains a viable firm in the market. In *Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585 (1985),* plaintiff firm, who was victorious, lost market share but remained as a rival; *Allied Tube & Conduit Corp. v. Indian Head, 486 U.S. 492 (1988)* (finding no requirement that plastic tube maker be completely ousted from conduit market); *Wilk v. American Medical Ass'n, 895 F.2d 352* (7th Cir.) (finding no requirement that excluded chiropractors be unable to practice their profession), cert. denied, *496 U.S. 927 (1990).*

n185 See *Allied Tube, 486 U.S. 492.* See supra text accompanying notes 62-67.

n186 See generally 2A Phillip E. Areeda, Herbert Hovenkamp & John Solow, Antitrust Law, ch. 5 (rev. ed. 1995).

n187 E.g., *United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377 (1956); United States v. Aluminum Co. of America, 148 F.2d416 (2d Cir. 1945).* See Areeda, supra note 146; Hovenkamp, supra note 1, at ch. 3.

n188 See *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., 113 S. Ct. 2578 (1993);* Areeda & Hovenkamp, supra note 129, paragraph 711.2.

n189 *FTC v. Indiana Federation of Dentists, 476 U.S. 447, 458 (1986).* See also *Nat'! Society of Professional Engineers v. United States, 435 U.S. 679, 692693 (1978)* (purporting to apply rule of reason to condemn ethical canon forbidding competitive bidding); *Goldfarb v. Virginia State Bar, 421 U.S. 773, 778 and n.17, 781-782 (1975)* (suggesting rule of reason treatment for learned professions).

n190 *476 U.S. at 459.*

n191 Alternatively, the Court noted that in two Indiana localities the dentists in the Federation constituted heavy majorities of practicing dentists and that, as a result, of the Federation policy, insurers had difficulty obtaining compliance with their request for x-rays. *Id. at 460.*

n192 *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Oklahoma, 468 U.S. 85 (1984).*

n193 *468 U.S. at 109.*

n194 *Id. at 110.*

n195 *Id. at 111.* See *546 F. Supp. at 1297-1300.*

n196 *Northwest Wholesale Stationers v. Pacific Stationery & Printing Co., 472 U.S. 284 (1985).*

n197 *472 U.S. at 294* (quoting Lawrence Anthony Sullivan, Handbook of the Law of Antitrust 261-262 (1977)).

n198 *472 U.S. 294.*

n199 *Id. at 295.*

n200 Id. at 296.

n201 The Supreme Court's decision in *FTC v. Superior Ct. Trial Lawyers Ass'n, 493 U.S. 411 (1990),* established this proposition. This decision, which applied the per se rule to an agreement of trial lawyers to withhold representation of indigent criminal defendants until the fee schedule was modified, did not begin with a joint venture that was presumed to have integrative or other efficiency effects.

n202 Id.

n203 *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Okla., 468 U.S. 85, 109 (1984).*

n204 For example, if the NCAA joint venture agreement included a provision fixing general tuition rates at participating colleges, quick per se condemnation would be in order.

n205 See, e.g., *Montague & Co. v. Lowry, 193 U.S. 38 (1904)* (finding invalid an association of tile dealers that agreed not to sell to non-members).

n206 *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1, 19-20 (1979).*

n207 On the relationship between persistent price discrimination and market power, see Phillip E. Areeda, Herbert Hovenkamp & John Solow, Antitrust Law paragraph 522 (rev. ed. 1995).

n208 The Lerner Index quantifies market power according to the formula L = (P-MC)/P, where L is the index reading (from zero to one), P is the firm's profitmaximizing price, and MC is the firm's marginal cost at its profit-maximizing price. A perfect competitor's price equals its marginal cost, so the index reads zero. As P becomes very much greater than MC, the index approaches one. For further development see Phillip E. Areeda, Herbert Hovenkamp & John Solow, supra note 207, paragraph 503; Hovenkamp, supra note 1, section 3. la.

n209 See 2A Areeda et al., supra note 146, paragraph 506d.

n210 1992 Horizontal Merger Guidelines, section 1.11, *57 Fed. Reg. 41,552-01, 41,554 (1992).*

n211 Id. section 1.32.

n212 Id. section 3.2. The two year interval measures entry from initial planning by the new entrant to "significant market impact." Id.

n213 See Kenneth G. Elzinga & David E. Mills, Testing for Predation: is Recoupment Feasible?, *34 Antitrust Bull. 869 (1989);* Hovenkamp, supra note 1, sections 8.4, 8.7, 8.8.

n214 For divergent perspectives, see Michael L. Denger and John A. Herfort, Predatory Pricing Claims After Brooke Group, *62 Antitrust* L.J. *541 (1994);* Jonathan B. Baker, Predatory Pricing After Brooke Group: an Economic Perspective, *62 Antitrust L.J. 585 (1994);* Kenneth L. Glazer,

Predatory Pricing and Beyond: Life after Brooke Group, *62 Antitrust* lj. *605 (1994).*

n215 As Judge Easterbrook once noted concerning the Matsushita case, some twenty years of alleged predation could not have been profitable unless the defendants acquired the ability to charge monopoly prices for the indefinite future. Frank Easterbrook, The Limits of Antitrust, *63 Texas L. Rev. 1, 27 (1984).*

n216 Of course, when the joint venture itself is accused of engaging in an exclusionary practice such as predatory pricing, then the reverse is true: predatory pricing is at least as costly for the joint venture as for the individual firm; for in addition to the costs of the predation itself, the venturers must bear the costs of developing and implementing a joint strategy. See, e.g., *Matsushita Electric Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 588-589 (1986).*

n217 See supra Part II.B.

n218 *United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956).*

n219 *Allied Tube & Conduit Corp. v. Indian Head, 486 U.S. 492 (1988).* See supra text accompanying notes 161-85.

n220 The plastic conduit maker, having the lower costs, faces a residual demand curve (computed by taking the supply of steel at any given price as given) from which it computes its profit maximizing price. If the cost curve for steel is horizontal, that price will probably exclude steel from the market altogether, as Figure 4 illustrates. $SS Figure 4 $SE

Ss is the supply (or cost) of steel conduit, while MCp is the cost of plastic. If the plastic conduit maker sets a price

slightly below Ss, it will exclude the steel conduit makers altogether. If its price is any higher, however, it will not be able to limit the amount of steel that is sold, and the steel makers would produce Q, leaving the plastic conduit maker with nothing, notwithstanding its lower costs. This is simply another way of saying that the "residual" demand for plastic conduit, or the demand curve facing the plastic conduit manufacturer taking into account the productive capabilities of the steel conduit manufacturers, is the kinked line P-X-D.

Figure 5 illustrates the outcome if the cost curve for steel is rising. In that case the plastic conduit maker's profit-maximizing price may permit a certain amount of steel conduit to be sold. However, the quantity of steel conduit sold would be reduced dramatically. $SS Figure 5 $SE

In this figure Ss is the supply (or cost) of steel, while MCp is the cost of plastic. Line A-D' shows the "residual" demand for plastic conduit -- that is, the sales of plastic after the steel makers' ability to produce and sell has been taken into account. The Plastic conduit maker would maximize its profits at a price of P', which would permit 0-X units of steel to be sold in the market, and X-Z units of plastic to be sold. The steel makers' loss of output would equal X-Y, and their price would drop from A to P'.

n221 Figure 2, supra note 59, illustrates the consequences for a group of competitive firms whose demand is dramatically reduced. Demand curve D is the demand for steel conduit before plastic enters the market; demand curve D' is the demand for steel conduit after plastic enter. Now, the firms in the market must divide up output Q' rather than output Q. This could mean proportionately reduced output for all, perhaps entailing higher costs from excess capacity or failure to pay fixed costs associated with this excess capacity; it could also entail bankruptcy or plant closure for some firms.

n222 See supra discussion in Part IV.C.

n223 Figure 6 illustrates that the welfare loss from joint venture exclusion does not depend on the absence of competition within the venture. Demand curve D is the demand for steel conduit. Demand curve D', which is higher and to the right, is the demand curve for plastic conduit, or some mixture of plastic and steel. Assuming costs and price equal to MC -- that is, perfect competition -- consumers' surplus equals B-P-C for steel conduit and A-P-D for plastic, or the plastic-steel combination. The welfare loss is the rhombus A-B-C-D.

[SEE FIGURE IN ORIGINAL]

If the steel conduit maker had been a monopolist or cartel, the introduction of a competitively behaving maker of plastic conduit would have even greater effects. Not only would it create the welfare gains in Figure 6 but it would also force the steel monopolist or cartel to behave competitively.

n224 *United States v. E.L du Pont de Nemours & Co., 351 U.S. 377 (1956).*

n225 *Id. at 391.*

n226 That is, insurance coverage of losses that occurred before the policy issued, but that were discovered or for which suit was brought during the policy period.

n227 See *Hartford Fire Ins. Co. v. California, 113 S. Ct. 2891 (1913),* discussed supra text accompanying notes 68-71.

n228 Of course, in the case of insurance, where the product can be reconfigured on short notice, the dominant insurers may have little previous investment at risk of being

lost to a new innovation. In that case, the ability to collude may be their only incentive for keeping the broader insurance coverage off the market. By contrast, the makers of steel conduit may profit from excluding plastic even if they have no ability to collude themselves. They are at risk of losing their investment in steel technology to a rival with a superior product. The same thing generally applies to the excluded innovator whose innovation gives it lower costs than the dominant firms have.

n229 Further, the association does not need to detect every single instance of cheating, but only a substantial number of instances.

n230 E.g., *Goldfarb v. Virginia State Bar, 421 U.S. 773 (1975)* (striking down minimum legal fees imposed by bar).

n231 Once BMI obtained the license from individual composers, artists, or other performance right holders, it issued a blanket license permitting any licensee (such as a radio or television station) to play anything in BMI's repertoire, by paying a fee that varied with the station's revenue. *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1, 5 (1979).*

n232 See, e.g., *Nat'l Macaroni Mfrs. Assoc., 65 F.T.C. 583 (1964),* affd, *345 F.2d 421, 423 (7th Cir. 1965)* (condemning an agreement by 84 macaroni makers in association to make their product of 50% hard (durum) wheat, and 50% cheaper, soft wheat).

n233 One might also look at such market facts as the size and secrecy of sales transactions, the extent to which firms discounted from their published prices, the sophistication of buyers, and the like. It might also be relevant how many members actually published their price lists in the appendix, or if members felt constrained in any

way to publish them. For example, the threat of collusion would be significantly greater if three out of three manufacturers of double-pole switches published, than if three out of 200 manufacturers of electric wire published.

On industry conditions conducive to collusion, see Areeda, supra note 146, paragraphs 1430-1431; Hovenkamp, supra note 1, sections 4.2-4.6.

n234 A corollary is that one ordinarily combines all brands or product varieties that the venture's members issue. For example, in the Discover/VISA litigation, the district court observed that virtually every issuer of a VISA also issued a MasterCard. Visa's share of the relevant product market, defined as general purpose charge cards, was 45.6% while MasterCard's was 25.4%. (The others were American Express, 20.5%; Discover Card, 5.5%; and Diners Club, 2.0%). The court correctly concluded that, for this particular litigation, the market share of the defendant should be reckoned at 71%, or the sum of Visa and MasterCard. That is, to the extent each Visa decision maker also issued a MasterCard, it was acting in its capacity as issuer of both cards. The fact that the rule that was passed issued only from these banks acting in their "VISAissuer" capacity rather than their "MasterCard-issuer" capacity is irrelevant.

The important premise, of course, is that VISA and MasterCard are substitute products. For example, suppose that gasoline and gasohol (which contains 10% ethanol) are regarded by most customers as nearly perfect substitutes, and most gasoline stations sell both. If the relevant market were defined to include both products, any challenge to a joint venture among stations would compute market share by aggregating sales of gasoline and gasohol, even if the rule being challenged applied only to one. By contrast, if two products were not substitutes, sales of the product

unaffected by the venture rule would be excluded. So, for example, the stations' sales of tires would not be taken into account.

n235 *SCFC 1LC, Inc. v. VISA U.S.A., 36 F.3d 958 (1Oth Cir. 1994).*

n236 *Id. at 967-68.*

n237 See supra text accompanying notes 145-47.

n238 The HHI is computed by squaring and then summing the market shares of each firm (or venture) in the market. Suppose, for example, that a market contained two production joint ventures that accounted for 25% of the market each, and 5 individual firms that accounted for 10% each. The HHI would be 252 + 252 + 102 + 102 + 102 + 102 + 102, or 1750. See 1992 Horizontal Merger Guidelines, section 1.51, supra note 210, at 41,558.

In some circumstances, an 1800 I-IHI threshold may be too tolerant. For example, at that level the venture could have a market share on the order of 40%, and a fringe of smaller firms could make up the balance. Such a venture could have substantial room to set price above cost.

n239 Guidelines recently issued by the DOJ and the FTC are somewhat less tolerant. Draft Antitrust Guidelines for the Licensing and Acquisition of Intellectual Property, section 4.1, supra note 23, at 41,344 (creating safety zone only where licensor and its licensees collectively account for 20% of relevant market); DOJ and FTC, Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust, Policy on Physician Network Joint Ventures, part A (Sept. 27, 1994) (20% safety zone for physician network joint ventures).

n240 See Baker, note 19, at 1073; Gregory J. Werden, The Law and Economics of the Essential Facilities Doctrine, *32 St. Louis L.J. 433, 473 (1987)* (making the same point with respect to essential facilities).

n241 Contra *SCFC ILC, Inc. v. VISA U.S.A., Inc., 36 F.3d 958 (lOth Cir. 1994)* (accepting free rider argument by citing only the fact that if Dean Witter entered Visa it would have access to Visa's distribution system, which is of course what all Visa issuers access; no explanation of why this constitutes free riding).

n242 See Lester Telser, Why Should Manufacturers Want Fair Trade? *3 J.L. & Econ. 86 (1960);* Hovenkamp, supra note 1, section 11.3a.

n243 On the output effects of free riding by dealers, see Hovenkamp, supra note 1.

n244 E.g., *General Leaseways, Inc. v. Nat'l Truck Leasing Ass'n, 744 F.2d 588 (7th Cir. 1984)* (efficient joint venture for repair of rental trucks, but condemning horizontal territorial division agreement; plaintiff had been denied right to open outlet in territory of another member). If the venture is inherently conducive to collusion, of course, judicial destruction of the venture may be the only available solution.

n245 See, e.g, *SCFC ILC, Inc. v. VISA U.S.A., Inc., 819 F. Supp. 956 (D. Utah 1993),* rev'd, *36 F.3d 958 (lOth Cir. 1994); MasterCard International, Inc. v. Dean Witter, Discover & Co., 1993 W.L 338213 (S.D.N.Y. 1993); Worthen Bank & Trust Co. v. Nat'l Bank Americard, Inc., 485 F.2d 119 (8th Cir. 1973),* cert. denied, *415 U.S. 918 (1974).*

n246 The NFL's refusal to admit a new member is generally justified, not by free rider concerns, but by the fact that a new member does not compete with existing members. See infra text accompanying notes 268-70.

n247 On market share thresholds, see supra text accompanying notes 238-39.

n248 Real estate multiple listing services are joint ventures in which participating realtors share "listing" information showing properties that are for sale, and generally agree that members will be able to show one another's listings and sell them subject to pre-arranged commission splits. A real estate firm excluded from a multiple listing service is effectively limited to showing and selling its own listings. See *In re Florence Multiple Listing Serv., Inc., 110 F.T.C. 493 (1988)* (using a consent decree to forbid multiple listing service from requiring vote on membership and insisting that applicant not compete with the multiple listing service); see *Thompson v. Metropolitan Multi-List, 934 F.2d 1566 (11th Cir. 1991)* (recognizing possible boycott claim); *United States v. Realty Multi-List, Inc., 629 F.2d 1351 (5th Cir. 1980)* (same), cert. denied, *113 S. Ct. 295 (1992).*

n249 See supra text accompanying notes 62-67.

n250 See *SCFC ILC, Inc. v. VISA U.S.A., Inc., 819 F. Supp. 956, 964 (D.Utah 1993),* rev'd, *36 F.3d 958 (lOth Cir. 1994).* See supra note 155.

n251 See supra Part IV.B.-C.

n252 *SCFC ILC, Inc. v. VISA U.S.A., Inc., 819 F. Supp. 956 (D. Utah 1993),* rev'd, *36 F.3d 958 (lOth Cir. 1994).* See supra Part IV.B.-C.

n253 *819 F. Supp. at 970.*

n254 *Id. at 963.*

n255 See *id. at 962.*

n256 *Id. at 964.*

n257 *Id. at 963-964.*

n258 "If permitted by applicable law, the corporation shall not accept for membership any applicant which is issuing, directly or indirectly, Discover Cards or American Express cards, or any other cards deemed competitive by the Board of Directors; an applicant shall be deemed to be issuing such cards if its parent, subsidiary or affiliate issues such cards." *Id. at 964.*

n259 Once again, the interests of the venture were different from the interests of its individual members. See supra Part IV.B.-C.

n260 E.g., *Chrysler Corp. v. General Motors Corp., 589 F. Supp. 1182 (D.D.C. 1984)* (dealing with a competitor challenge to production venture between rival GM and rival Toyota).

n261 If the cards were merely competitors, such packages would have no value.

n262 See, e.g., *NCAA v. Bd. of Regents of the University of Okla., 707 F.2d at 1161,* affd, *468 U.S. 85 (1984)* (rejecting NCAA's free rider evidence as "sham"; NCAA had control over a "minimum aggregate fee" that television network had to pay for television rights, and thus could reward some teams more than others).

n263 Numerous ventures have solved free riding problems by using membership fees designed to compensate the venture or other venture members for their investment. See, e.g., *United States v. Associated Press, 52 F. Supp. 362, 365 (1943).* See supra text accompanying note 101. See also *Chicago Professional Sports Limited Partnership & WGN v. Nat'l Basketball Ass'n, 961 F.2d 667* (7th Cir.) (rejecting free rider argument when sports league was able to charge teams for promotional services), cert. denied, *113 S. Ct. 409 (1992); General Leaseways, Inc. v. Nat'l Truck Leasing Ass'n, 744 F.2d 588 (7th Cir. 1984)* (rejecting free rider claims involving members' repairs of each other's trucks when they charged for the service).

n264 See Areeda, supra note 146. See also the position taken by the Justice Department in the proposed Intellectual Property Guidelines, section 4.4. "The existence of practical and significantly less restrictive alternatives is relevant to a determination of whether a restraint is reasonably necessary." Supra note 23, at 41,346.

n265 See Hovenkamp, supra note 1, at 54; Herbert Hovenkamp, The Sherman Act and the Classical Theory of Competition, *74 Iowa L. Rev. 1019, 1041-1044 (1989)* (noting that at common law restraints were "reasonable" only if they were no broader than necessary to protect the interest that was entitled to be protected).

n266 For example, in the Visa case the Tenth Circuit accepted the defendant's argument that excluding Discover Card from Visa membership was efficient because it prevented free riding: if Discover were to join Visa and become large enough, it might acquire a seat on Visa's board. In that case Discover might acquire access to Visa's intellectual property that could be used to benefit *Discover SCFC ILC, Inc. v. VISA U.S.A., Inc., 36 F.3d 958 (lOth Cir. 1994).*

n267 Cf. *Nat'l Bancard Corp. (NaBanco) v. Visa U.S.A., 779 F.2d 592* (1 lth Cir.) (upholding fixing of bank interchange fees without serious inquiry into whether there were alternative methods of communicating the fees, such as printing them on the back of the card), cert. denied, *479 U.S. 923 (1988).*

n268 See supra text accompanying note 118.

n269 See *Mid-South Grizzlies v. NFL, 720 F.2d 772 (3d Cir. 1983)* (denying a football team the right to join the NFL), cert denied, *467 U.S. 1215 (1984).*

n270 *Los Angeles Mem- Coliseum Comm'n. v. Nat'l Football League, 726 F.2d 1381* (9th Cir.) (disapproving rule requiring 3/4 of League members to approve a current member's request to move its team; prior to amendment, the rule also permitted any team to veto a different team's request to move into that team's home territory), cert. denied, *469 U.S. 990 (1984); North Am. Soccer League v. Nat'l Football League, 670 F.2d 1249* (2d Cir.), cert. denied, *459 U.S. 1074 (1982). Contrast Mid-South Grizzlies v. NFL, 720 F.2d 772 (3d Cir. 1983),* cert. denied, *467 U.S. 1215 (1984),* which denied a claim when the franchise applicant was from a town that did not already have an NFL franchise.

n271 *Associated Press v. United States, 326 U.S. 1 (1945);* see supra text accompanying notes 98-101.

n272 See Areeda & Hovenkamp, supra note 129, paragraphs 736.1-736.2 (criticizing the so-called "essential facility" doctrine).

n273 See, for example, the following cases ordered chronologically: *United States v. Terminal R.R. Ass'n, 224 U.S. 383 (1912); Otter Tail Power Co. v. United States, 410 U.S. 366 (1973); MCI Communications Co. v. AT&T, 708 F.2d 1081, 1132 (7th Cir. 1982£* cert. denied, *464 U.S. 891 (1983); United States*

v. AT&T, 552 F. Supp. 131 (D.D.C. 1982£ affd mem. sub nom. *Maryland v. United States, 460 U.S. 1001 (1983).*

n274 For example, see supra Figure 5 accompanying note 220.

n275 See *Mid-South Grizzlies v. NFL, 720 F.2d 772 (3d Cir. 1983),* cert. denied, *467 U.S. 1215 (1984);* accord *Seattle Totems Hockey Club v. Nat'l Hockey League, 783 F.2d 1347* (9th Cir.), cert. denied, *479 U.S. 932 (1986).*

n276 Such a local government could be liable in antitrust under the "state action" doctrine. See 4 Phillip E. Areeda & Donald F. Turner, Antitrust Law paragraph 917, at 85 (1980); and Hovenkamp, supra note 1, section 20.6.

n277 See *City of Malden, Mo. v. Union Elec. Co., 887 F.2d 157 (8th Cir. 1989)* (finding no essential facility violation where plaintiff could economically operate its own system).

n278 *United States v. Terminal R.R. Ass'n, 224 U.S. 383 (1912);* see supra text accompanying notes 92-94.

n279 However, for evidence that it was not, particularly for through traffic, see supra text accompanying note 93.

n280 On this requirement, see Hovenkamp, supra note 6, at ch. 10.

n281 *Associated Press v. United States, 326 U.S. 1 (1945);* see supra text accompanying notes 104-18.

n282 E.g., *Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263 (2d Cir. 1979)* (manufacturers of complimentary products), cert. denied, *444 U.S. 1093 (1980).*

n283 As is generally the case in professional sports, where teams do not compete for gate receipts.

n284 The Supreme Court failed to see this in *Continental T.V.v. GTE Sylvania Inc., 433 U.S. 36 (1977),* where it suggested that in a vertical restraint rule of reason case interbrand and intrabrand competition must somehow be "balanced" against each other. That is to say, spacing Sylvania dealers further apart was thought to injure intrabrand competition somehow, but it was done for the benefit of interbrand competition. But the Court was confusing "competition" with number of rivals. It certainly didn't mean that vertically imposed location restrictions tended to increase the price of Sylvania's above the competitive level if one looked at brands, but tended to decrease their price if one looked at the entire market for televisions.

n285 *Worthen Bank & Trust Co. v. Nat'l Bankamericard, Inc., 345 F. Supp. 1309 (E.D. Ark. 1972),* rev'd, *485 F.2d 119 (8th Cir.1973),* cert. denied, *415 U.S. 918, 94 S. Ct. 1417, 39 LEd.2d 473 (1974).*

n286 For the history of this change, see *SCFC ILC, Inc. v. Visa U.S.A., Inc., 819 F. Supp. 956, 963,* rev'd, *36 F.3d 958 (lOth Cir. 1994).*

n287 Id.

n288 See *Nat'l Bancard Corp. (NaBanco) v. VISA U.S.A., 779 F.2d 592* (1 lth Cir.), cert. denied, *479 U.S. 923 (1986);* William F. Baxter, Bank Interchange of Transactional Paper: Legal and Economic Perspectives, *26* J.L. & *Econ. 541 (1981).*

n289 See supra text accompanying notes 109-17.

n290 E.g., Baker, supra note 19.

n291 See supra Part III.B.

n292 See supra text accompanying notes 109-17.

n293 In *SCFC ILC, Inc. v. VISA U.S.A., Inc., 819 F. Supp. 956 (D. Utah 1993)*, rev'd, *36 F.3d 958 (lOth Cir. 1994)*, VISA defended its policy of excluding issuers of competing cards as members by saying that the policy would facilitate the development of rival systems. If VISA really anticipated that the effect of its exclusivity rule would be to encourage the emergence of rival Discover, it would have dropped the rule.

n294 E.g., Baker, supra note 19, at 1004. See also Mary Azcuenaga, Essential Facilities and Regulation: Court or Agency Jurisdiction, *58 Antitrust L.J. 879, 880-886 (1989)*.

n295 See Donald A. Turner, The Definition of Agreement Under the Sherman Act: Conscious Parallelism and Refusals to Deal, *75 Harv. L. Rev. 655 (1962)*; and Carl Kaysen & Donald A. Turner, Antitrust Policy 110-119, 266-272 (1959).

Likewise, Judge Wyzanski was probably asking for trouble when he ordered United Shoe Machinery to offer its equipment for sale on terms equivalent to those that it offered upon lease. *United States v. United Shoe Machinery Co., 110 F. Supp. 295, 340, 341, 348-351 (D.Mass. 1953)*, affirmed per curiam, *347 U.S. 521, 74 S. Ct. 699 (1954)*; see also Carl Kaysen, United States v. United Shoe Machinery Corporation: an Economic Analysis of an Antitrust Case 13-16, 75-76 (1956).

n296 See supra Part VI.B.

n297 For these reasons the common law of regulation did not regulate prices, but it did prohibit "unfair

discrimination," which occurred when a natural firm charged different prices for products or services that were manifestly the same. Setting a price is extremely different, but equalizing the playing field is often less so. See Hovenkamp, supra note 6, at ch. 11.

n298 E.g., *Bolt v. Halifax Medical Center, 891 F.2d 810* (1 lth Cir.) (finding that physicians with separate economic interests voted to exclude the plaintiff), cert. denied, *495 U.S. 924 (1990).*

n299 For example, home owners' associations often make admission decisions by voting, but the Fair Housing Act forbids them from discriminating on the basis of race. This thrusts upon the courts the difficult job of determining whether a particular exclusion resulting from a vote was racially motivated. See, e.g., *Robinson v. 12 Lofis Realty, Inc., 610 F.2d 1032 (2d Cir. 1979)* (requiring the lower court to examine the vote of a home owners' association excluding a black applicant, to see if it was motivated by racial bias). No one has seriously suggested either that the race discrimination be permitted or that home owners' associations be forbidden from making decisions by vote. The courts simply must manage the problem.

n300 E.g., *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Oklahoma, 468 U.S. 85 (1984)* (finding output reduction was naked restraint); see supra text accompanying notes 192-95; *W. W. Montague & Co. v. Lowry, 193 U.S. 38, 38 (1904)* (finding that an association organized to advance the interests of its members "by frequent interchange of ideas" violated the Sherman Act by refusing to deal with any non-member of the association, or to charge them only full list prices, which were 50% higher than prevailing market prices).

n301 On the more general analysis, see 7 Areeda, supra note 233, paragraph 1511; Hovenkamp, supra note 1, section 5.6c.

n302 See *FTC v. Indiana Federation of Dentists, 476 U.S. 447, 458 (1986); Northwest Wholesale Stationers v. Pacific Stationery & Printing Co., 472 U.S. 284 (1985).*

n303 *FTC v. Superior Ct. Trial Lawyers Ass'n, 493 U.S. 411 (1990).*

n304 Even this narrowly stated per se rule seems inconsistent with *Northwest Wholesale Stationers v. Pacific Stationery & Printing Co., 472 U.S. 284 (1985),* which appeared to assess a market power requirement even for a completely unexplained refusal to deal. But the Court gave the benefit of the doubt to the defendants, and was not willing to infer that the refusal was a simple cartel facilitator merely from the fact that it was unexplained. In any event, the Trial Lawyers decision makes clear that there is still room for per se analysis of refusals to deal used as naked cartel facilitators. *493 U.S. 411.*

n305 See generally Areeda et al., supra note 186, at ch. 5.

n306 Presumptively, 'dismissal seems warranted if the market has a system level HHI of less than 1800, and the share of the market controlled by the venture is less than 25%. See supra text accompanying notes 238-39.

n307 See supra Part VII.

n308 For example, the founding members of an open membership joint venture should be able to charge a fee designed to compensate themselves for entry risks.

n309 One might think of idiosyncratic exceptions, such as the venturers who operate in multiple markets and the applicant who competes in some market other than the one covered by the venture.

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ARTICLE: UNDERSTANDING JUDICIAL REVIEW OF HOSPITALS' PHYSICIAN CREDENTIALING AND PEER REVIEW DECISIONS

Craig W. Dallon*

* Assistant Professor of Law, Creighton University School of Law. B.A., Brigham Young University; J.D., Brigham Young University. My thanks go to Byron Martin and Colette Neish for their research and editing assistance in preparing this Article.

SUMMARY:

... A hospital's organized medical staff plays a vital role in the hospital's mission as a health care provider and also directly affects consumers of the hospital's health care services .... The Meaning of Medical Staff Membership... Second, medical staff membership gives the physician a voice in the operation of the hospital .... A few courts reason that, because the hospital is required by state law to adopt medical staff bylaws and, in some instances, even to have a particular minimum content, the rights provided for in the bylaws cannot legally constitute valid consideration. Not only does state law require medical staff bylaws, but the hospital accrediting body, the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), also requires medical staff bylaws and to some extent defines

their content .... Although state law, JCAHO standards, and federal regulations may require adoption of medical staff bylaws, their precise form and content are left largely to the hospital and its medical staff .... Furthermore, the physician who is a member of the medical staff (as contrasted with an initial applicant) actually does have the opportunity to influence the content of the medical staff bylaws .... The Supreme Court of South Dakota held that the unilaterally-adopted bylaws were "null and void," and it concluded that any changes had to be approved by the medical staff in compliance with the two-thirds majority requirement in the original bylaws ....

TEXT:
[*598]

Introduction

A hospital's organized medical staff plays a vital role in the hospital's mission as a health care provider and also directly affects consumers of the hospital's health care services. Two important functions of a medical staff are making credentialing decisions and conducting peer review. Credentialing decisions determine who is granted or retains staff membership and the level of practice privileges the staff member enjoys, n1 Peer review is a broader concept involving review by medical staff members of the quality and effectiveness of services performed by other medical staff members. n2 Although peer review in hospitals occurs in many contexts, the focus of this Article will be a hospital's credentialing and peer review decisions resulting in the denial, limitation, suspension, revocation, or nonrenewal of a physician's medical staff or clinical [*599] privileges and the extent of judicial review of those decisions.

A physician seeking medical staff membership or clinical privileges goes through an application process, n3 During this process, the hospital evaluates the physician's qualifications and background, n4 Ultimately, privileges may be granted or denied. Furthermore, staff members with existing privileges are subject to regular reevaluation, n5 When a hospital's medical staff, through peer review efforts or as a result of other information, becomes aware of health care quality concerns involving an individual staff member, it should investigate the concerns and take any necessary action. Possible actions include limitation, suspension, revocation, or nonrenewal of staff privileges, n6 Such adverse actions involving staff privileges have a direct and potentially devastating impact on the staff member's practice, n7 Frequently, the affected practitioner will exercise whatever administrative or judicial review options are available in an effort to overturn the decision. The issue then becomes the extent to which a court will review a hospital's decision adversely affecting staff privileges.

Part I of this Article identifies the problem and provides its historical background. Part II identifies the competing interests of physicians, hospitals, and the public in the credentialing and peer review processes that influence how courts deal with challenges to credentialing decisions. In Part III, the Article identifies and examines the various legal theories for judicial review of physician credentialing decisions including: constitutional due process, the rule of non-review, breach of contract, fiduciary duty, common law fairness, and statutory review. Finally, in Part IV, the Article concludes that due process review, rooted in constitutional principles in cases involving public hospitals and in contract in cases featuring private hospitals, provides an appropriate framework for judicial review. This due process review should be afforded to both initial applicants and staff members with existing privileges.

I. Hospital Medical Staffs and the Credentialing Process

A. The Hospital-Physician Relationship and the Organization of Medical Staffs

1. Historical Development of the Hospital-Physician Relationship

Until the late nineteenth century, hospitals were usually charitable [*600] institutions providing free health care to the poor. n8 Most of these early hospitals lacked what has become known as self-governing, organized medical staffs, n9 One authority described these pre-twentieth century hospitals as ""boarding houses.., unworthy of the confidence and support of their communities.'" nl0 According to Loyal Davis, they "were conducted in a manner which brought discredit upon the medical profession." nl 1 Prior to the beginning of the twentieth century, a physician performed most of his work outside of hospitals in the physician's office or private individuals' homes n12 and thus, a physician's practice did not require access to a hospital. Paul Starr estimates that in the 1870s as few as two percent of American physicians had hospital privileges, n13 Physicians even performed surgeries in homes, often in the kitchen, n14 Both the public and physicians often held a dim view of hospitals, n15 According to Paul Starr, "before 1900 the hospital had no special advantages over the home, and the infections that periodically swept through hospital wards made physicians cautious about sending patients there." n16

However, with medical advances, particularly in the area of surgery, the demand for hospitals increased substantially. n17 Services became more [*601]specialized as hospitals transformed themselves from asylums for the indigent into "citadels of healing." n18 According to Paul

Starr, "roughly between 1870 and 1910, hospitals moved from the periphery to the center of medical education and medical practice." n19 Starr adds that these hospitals evolved "from refuges mainly for the homeless poor and insane.., into doctors' workshops for all types and classes of patients." n20 As part of the move away from their role as primarily charitable institutions, hospitals began to allow physicians to charge patients for services rendered in hospitals, n21 thus hospital privileges became more important to physicians. With medical advances, "the conscientious physician became increasingly dependent on the diagnostic and therapeutic facilities which only a hospital could provide." n22

As this new demand for hospital services increased, the number of hospitals in the United States exploded, jumping from 178 in 1873, to 4359 in 1909, and to 6719 by 1930. n23 In the face of this rapid expansion, the American College of Surgeons ("ACS") was organized in 1913 with a primary objective to standardize hospital care. n24 Surgeons in particular believed that both hospitals and physicians performing surgeries should meet minimum standard requirements for safe equipment and safe performance of surgeries, n25 Beginning in 1917, the ACS established the voluntary "Minimum Standard" for hospitals, n26 In 1919, the ['602]ACS established the Hospital Standardization Program ("HSP") to carry out its goal of hospital standardization by studying and monitoring hospitals and building on the Minimum Standard. n27 The HSP was the predecessor of what is now known as the Joint Commission On Accreditation of Healthcare Organizations ("JCAHO"). n28 The Minimum Standard stressed self-regulation through organized medical staffs, n29 For instance, it required "that physicians and surgeons privileged to practice in the hospital be organized as a definite medical staff' and "that the medical staff initiate and, with the approval of the governing board of the hospital, adopt rules,

regulations, and policies governing the professional work of the hospital." n30 From 1918 to 1935, largely in response to the ACS's standardization initiative, the percentage of hospitals with organized medical staffs increased from twenty percent to ninety percent of the hospitals surveyed by the HSP. n31

Prior to organized medical staffs and hospital standardization, some "open staff" hospitals allowed nearly any physician - regardless of qualifications - the privilege of admitting and caring for private paying patients in the hospital, n32 [*603] while many "closed staff" hospitals made staff appointments often based on "favoritism rather than skill." n33 Standardization addressed this lack of standards by imposing requirements for membership on the medical staff and by encouraging "collective responsibility for standards among the "open staff' itself." n34 The Minimum Standard required:

That membership upon the medical staff be restricted to physicians and surgeons who are (a) graduates of medicine of approved medical schools, with the degree of Doctor of Medicine, in good standing, and legally licensed to practice in their respective states or provinces; (b) competent in their respective fields; and (c) worthy in character and in matters of professional ethics;.., n35

A central purpose of hospital standardization was to "prevent[ ] hospitals from being imposed upon by incompetent physicians," n36 and, in turn, to protect the public. Early supporters of hospital standardization were motivated not only genuine concern for the quality of care provided to patients, but also the need to assure the public that hospitals were safe and worthy of the public's patronage. JCAHO has continued to emphasize the necessity for independent, self-governing medical staffs at hospitals. The medical staff has "overall responsibility for

the quality of the professional services provided by individuals with clinical privileges, as well as the responsibility of accounting therefore to the governing body." n37 JCAHO's Accreditation Manual for Hospitals contains a chapter with numerous standards governing medical staffs, n38 The influence of JCAHO accreditation requirements, including those governing medical staffs, is considerable. Although JCAHO is a private nonprofit corporation and hospitals are not required to obtain JCAHO accreditation, the great majority of hospitals do seek and receive accreditation, n39 JCAHO accreditation affords substantial advantages to hospitals including eligibility to receive Medicare payments and recognition under state licensing requirements, n40 States, as part of their hospital [*604] licensure regulations, also require the organization of medical staffs and define the staff's role. n41

2. The Meaning of Medical Staff Membership

The medical staff consists of "fully licensed physicians and may include other licensed individuals permitted by law and by the hospital to provide patient care services independently in the hospital." n42 Although this Article will refer primarily to physicians (both medical doctors and osteopathic doctors), n43 hospital staffs, depending upon state law and the hospital's own bylaws, also may include dentists, podiatrists, psychologists, and other health care professionals. n44

[*605] Medical staff membership normally does not create an employment relationship with the hospital, n45 Instead, it represents membership in an organization that affords certain rights and responsibilities. As one court explained:

Staff privileges serve to delimit a doctor's authority to practice in the hospital based upon the doctor's overall competence in his particular field(s) of practice. Staff privileges do not establish an employment contract with the hospital... Rather, the use a doctor makes of his staff privileges depends upon some independent source. In the case of a physician or surgeon, that independent source is typically the operation of his private practice. In the case of a pathologist that source may be some independent contractual arrangement with the hospital.., n46

A physician's relationship with a hospital based solely on staff membership and corresponding clinical privileges lacks the traditional elements of an employment relationship, n47 Perhaps most significantly, the hospital does not direct or control the details of a physician's medical practice, n48 Although the [*606] hospital makes its facilities available to the physician and imposes certain professional standards, n49 the physician is paid directly by individual patients or insurers and independently diagnoses, admits, and prescribes the course of treatment for his or her patients, n50 Conversely, the hospital does not bill patients for the physician's services, pay the physician, provide retirement or insurance benefits for the physician, select the physician's patients, set the physician's schedule, or control or direct the manner in which the physician provides services, n51

The assumption that individual medical staff members act independently and therefore without undue interference from the hospital serves as the foundation for the concept of an organized medical staff. By definition, the medical staff consists of "licensed independent practitioners" who are authorized "to provide care and services without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges." n52

Viewing medical staff members as non-employees of the hospital is consistent with the historical development of modern American hospitals. Over time, hospitals offering charitable care without cost began to rely upon revenue [*607]from private rooms used by patients admitted by private practitioners, n53 These private rooms in many cases were available for patients of "almost any private physician," and "there was no systematic policy in voluntary hospitals toward exercise of controls over the work of private physicians." n54 Although policies and minimum standards were later imposed, the physician has continued to exercise significant autonomy over the care administered to individual patients at the hospital, n55

Of course, a physician who is a member of the medical staff also may be an employee of the hospital, but that employment relationship is created separately, n56 Indeed, in recent years, with the increased pressures toward managed care and vertical consolidation in the healthcare industry, more and more physicians are becoming employees of hospitals, n57 A physician who, in addition to staff membership, also has an employment relationship with the hospital obviously has an employment contract and employment law remedies.

Membership on a hospital medical staff affords important advantages. First, staff membership is a prerequisite for a physician to admit patients to the hospital and provide health care services in the hospital, n58 Individual members of the medical staff are granted specific "clinical privileges" according to their [*608] license, education, training, experience, competence, health status, and judgment, n59 These delineated privileges are authorization for "a practitioner to provide specific care services.., within well-defined limits." n60 Staff membership and clinical privileges are related but separate concepts. The grant of medical staff membership does not assure the grant

of any particular requested clinical privileges, n61 Different staff members are entitled to different clinical privileges; a member of a medical staff who is a radiologist may be granted clinical privileges in radiology but not, for example, in anesthesiology. A physician may have clinical privileges to conduct certain specified surgeries, but not other types of surgeries, n62 Importantly, medical staff members who admit patients must be granted specific privileges to do so. n63 Members of the medical staff are then charged to be "intricately involved in carrying out, and in providing leadership in, all patient care functions conducted by individuals with clinical privileges." n64

Second, medical staff membership gives the physician a voice in the operation of the hospital. This voice transcends the fundamental fact that [*609] individual staff members supervise, direct, and perform the actual health care services provided to patients. The medical staff is an organized, self-governing collective that develops and adopts its own bylaws, rules, and regulations, n65 These staff strictures define the medical staffs role in the hospital. The bylaws establish, among other things: (1) a medical staff executive committee and define its functions; (2) "fair-hearing and appellate review mechanisms for medical staff members and other individuals holding clinical privileges"; (3) "mechanisms for corrective action, including indications and procedures for automatic and summary suspension of an individual's medical staff membership or clinical privileges"; (4) "the medical staffs organization, including categories of medical staff membership"; (5) "[a] mechanism designed to provide for effective communication among the medical staff, hospital administration, and governing body"; and (6) "medical staff representation and participation in any hospital deliberation affecting the discharge of medical staff responsibilities." n66 These provisions assure the medical staff the opportunity to participate in overall hospital operations.

A medical staff may have different categories of medical staff membership, each with different rights and privileges assigned to it. Both JCAHO standards and federal regulations require the identification of these categories and their corresponding qualifications and limitations in the medical staff bylaws, n67 The bylaws use various terms to describe these categories including attending staff, active staff, associate staff, consulting staff, courtesy staff, resident staff, or honorary staff, n68

B. The Credentialing Process - Becoming and Remaining a Member of the Medical Staff

The medical staffs ultimate purpose is to ensure and further the quality of patient care. The medical staff is "responsible to the governing body of the hospital for the quality of all health care provided to patients in the facility and for the ethical and professional practices of its members." n69 The medical staff ['610] shapes and implements admissions standards to the medical staff as well as requirements for clinical privileges, n70 This credentialing process entails "obtaining, verifying, and assessing the qualifications of a health care practitioner to provide patient care services in or for a health care organization." n71 Although the governing body of the hospital also participates in the credentialing process, the medical staff largely defines and controls the process, n72 Under JCAHO standards, "the mechanisms for appointment or reappointment and initial granting and renewal or revision of clinical privileges are approved and implemented by the medical staff and governing body." n73 As part of this process, the clinical departments recommend professional criteria for clinical privileges to the medical staff, n74 Ultimately the final decision to grant or deny staff membership or clinical privileges is made by the governing body of the hospital, but the governing body bases its decision on the recommendation of the medical staff, n75 A

hospital's governing body, usually a board, typically includes lay people, often prominent community members, who likely readily defer to the medical staff's recommendations. In short, the medical staff acts as a gatekeeper and, within certain parameters, effectively controls admission to its membership and grant of clinical privileges.

The medical staffs credentialing responsibility arises in several similar, yet factually distinct, contexts. First, the staff considers new applications for appointment to the medical staff from individuals who do not have current membership. In this initial application process the staff and the hospital consider ['611] information about the applicant's licensure, training, experience, competence, ability, professional ethics, reputation, and health status, n76 Many jurisdictions address the application process by statute and require procedural due process, n77 reasonableness standards and procedures, n78 impose timeframes for consideration of applications, n79 or impose other requirements on the hospital. n80

Second, the staff considers reappointments to staff membership for individuals with current membership. Usually a staff member's appointment is for a one or two year term. n81 Near the end of the term, the staff member goes through a reappointment process to renew staff privileges. In this process the medical staff considers an individual physician's "pattern of performance by analyzing claims filed against the physician, data dealing with utilization, quality, and risk, a review of clinical skills, adherence to hospital bylaws, policies and procedures, compliance with continuing education requirements, and mental and physical status." n82 This required, periodic

assessment results in a regular, systematic review of the competence and qualifications of staff members, n83 If a problem is identified, the hospital may take appropriate corrective measures.

Third, the medical staff considers action involving existing privileges any time problems are identified. The hospital and the medical staff have the responsibility to continuously review and monitor the professional performance of individual staff members and all medical services rendered at the hospital, n84 ['612] They fulfill this responsibility through ongoing utilization review and quality assurance mechanisms whereby the medical staff, through its committees or departments, reviews outcomes and specific cases to determine appropriateness of patient care. n85 If the quality of care provided by an individual staff member is questioned, the medical staff is required to investigate and take appropriate action which might include a recommendation that staff membership or clinical privileges be limited, revised, suspended, revoked, or not renewed, n86 The right of a hospital, upon recommendation of its medical staff, to take immediate action in the interest of patient safety and welfare is universally recognized. JCAHO standards require medical staff bylaws to include "mechanisms for corrective action, including indications and procedures for automatic and summary suspension of an individual's medical staff membership or clinical privileges." n87 State hospital licensing laws and regulations often specifically authorize hospitals to take immediate action when patient safety is jeopardized, n88

II. The Problem: Balancing Competing Interests of Physicians, Hospitals, and the Public

A. The Physician's Interest

A physician has an interest in being able to pursue his or her profession, n89 For the great majority of physicians, this interest requires access to hospital ['613] facilities, n90 That access requires staff membership and appropriate clinical privileges which are granted only by hospitals. In many areas, there may be only one hospital in a community, county, or region. Where there are no competing hospitals, denial or revocation of privileges may effectively prohibit the physician from participating in his or her profession in that community, n91

Even with the existence of competing hospitals, the negative implications of a denial or revocation of privileges remain because an adverse decision can have enormous consequences for the physician both at the hospital taking the adverse action and at other hospitals. Hospitals in the initial application and reapplication process require the physician to disclose any adverse actions taken involving the physician's professional license or privileges at any hospital, n92 Hospitals often contact other hospitals where applicants have previously practiced to verify the information provided by the physician, n93 Denial or revocation of privileges at another hospital alone may prevent the grant of privileges at a different hospital, n94

['614] Hospitals also check with state licensing officials, the National Federation of State Medical Boards Physician Disciplinary Data Bank, n95 and the National Practitioner Data Bank. n96 The Department of Health and Human Services established the National Practitioner Data Bank (hereinafter the "Data Bank") as required by the Health Care Quality Improvement Act (hereinafter "HCQIA" or the

"Act"). n97 The Act, passed in 1986, established a national reporting system to help prevent incompetent physicians from moving from state to state without discovery, n98 To encourage reporting to the Data Bank, HCQIA provides hospitals which comply with its requirements qualified immunity from damages resulting from the hospital's professional review actions, n99 Under HCQIA, a health care entity is required to report to the appropriate state board of medical examiners any "professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days." nl00 The Act ['615] and its implementing regulations provide that "the term "adversely affecting' includes reducing, restricting, suspending, revoking, denying, or failing to renew clinical privileges or membership in a health care entity." nl01

HCQIA, as well as the accompanying regulatory framework, requires the state board to report the information it receives to the Data Bank. n102 In addition to the professional review action information obtained indirectly from hospitals, the Data Bank also collects information about medical malpractice payments on behalf of physicians and actions taken by boards of medical examiners concerning a physician's license, n103 Although the information provided to the Data Bank is confidential, hospitals and others have access to the information under certain circumstances, n104 To enjoy the immunities extended by HCQIA, federal law requires hospitals to check with the Data Bank when a physician applies for staff or clinical privileges and every two years for physicians already on staff, n105 In addition to the strong encouragement of HCQIA, state laws require hospitals to report adverse actions involving a physician's privileges, n106 Failure to comply with these state law requirements may result in fines or loss of the hospital's license. n107

As a result of hospital practices, HCQIA, and state law, adverse action affecting a physician's staff membership or clinical privileges seriously affects a physician's ability to practice at any hospital, n108 In one case, at the invitation of a [*616] community hospital, a physician left his large city practice after ten years and began a practice at the community hospital, n109 After eight years of staff privileges at the hospital, the physician's privileges were summarily suspended, n110 The consequences to his practice were devastating:

The findings of fact show that immediately after his suspension [he] lost 25 percent of his patients, necessitating staff lay-offs at his clinic. Additionally, [he] lost his courtesy privileges at Odessa Hospital, and his application for staff privileges at Moses Lake Good Samaritan Hospital was put on hold until they received additional information on the Adams County suspension. [His] subsequent attempts to enroll in the United States Navy and the United States Air Force Physician Corps were similarly rebuffed for the same reason. In short, the summary suspension effectively deprived [him] of the pursuit of his medical practice. He was forced to take a low paying employment as a resident in training at the University of Southern California Medical School. n111

Because the effect upon a physician is so significant, physicians have an interest in ensuring fairness in the credentialing and peer review process, n112

B. The Hospital's Interest

1. Patient Welfare

The hospital also has an important interest in the credentialing process. Perhaps foremost, the hospital is concerned about the quality of health care services provided

in its facilities. This concern may have several motivations: (1) a genuine desire to fulfill the hospital's fundamental mission; (2) a desire to maintain and enhance the hospital's reputation in the community and among physicians, prospective patients, and the hospital's peers; (3) discharge of a hospital's legally imposed duty; (4) fear of liability to injured plaintiffs; and (5) the hospital's economic viability and ability to attract patients, n113 As noted ['617] later, n114 concern for the quality of health care and ultimately patient welfare, has resulted in great deference by courts to hospital credentialing decisions.

2. Hospital Liability

The hospital's interest in avoiding legal exposure resulting from improper screening or monitoring of medical staff members or, less directly, from improper care provided by medical staff members at the hospital has become increasingly important. Formerly, most hospitals enjoyed immunity from tort liability under the widely-accepted doctrines of charitable immunity n115 or governmental immunity, n116 By the 1940s, however, courts began to explicitly reject the charitable immunity doctrine, rendering hospitals liable for their own negligent acts and the negligent acts of their employees, n117 While a new development in many jurisdictions, allowing liability under these circumstances was by no means a radical move. Charitable immunity was, after all, an exception to the general rule that entities are liable for their own actions and the acts of their employees committed within the scope of the employees' employment, n118

The protection of governmental immunity is applicable, if at all, only to federal, state, county, or municipal hospitals. n119 This immunity persists, but, as ['618] with charitable immunity, the doctrine has substantially eroded, n120 Courts, however, did not stop

with the abrogation or limitation of immunities. Courts increasingly hold hospitals liable for the malpractice of medical staff members - non-employees of the hospital - in various factual contexts and under various theories, n121 A growing number of courts hold hospitals liable for the negligence of emergency room physicians even if those physicians are otherwise independent contractors and not hospital employees, n122 These courts have sometimes relied upon theories of "ostensible" or "apparent" agency, or "agency by estoppel" to bring the cases within the general rule of respondeat superior liability for acts of an agent, n123

Some courts have imposed a more sweeping rule under a "nondelegable duty" theory. Under this theory, where a hospital has a duty imposed by law or otherwise to provide physicians for emergency room care, the hospital is responsible for the quality of care provided by those physicians regardless of whether the physicians are the hospital's agents (employees) or not (independent contractors), n124 This approach removes the necessity to prove actual or apparent authority. In Jackson v. Power, n125 for example, the Alaska Supreme Court found that there was a genuine issue of fact whether the plaintiff [*619]reasonably believed that the physician at issue was the hospital's employee. n126 But, the court adopted the nondelegable duty theory and held the hospital vicariously liable as a matter of law for any malpractice committed by the emergency room attending physician, regardless of the physician's employment status, n127 Martin C. McWilliams and Hamilton E. Russell, III, have noted:

Although nondelegability of medical care has not swept the field, the determination of some courts that hospitals are, even under limited circumstances, subject to traditional nondelegable duty reflects changing perceptions of public policy at the most potent level. As the Ohio

Supreme Court observed in [Albian v. Flower Hospital], the movement is "toward imposing strict liability on hospitals" for medical care of patients, n128

Courts have also imposed liability on hospitals based on the acts of hospital non-employee medical staff members outside of the emergency room context. Some courts have based this expanded liability on the apparent authority doctrine. n129 Hospital liability has also expanded dramatically under the "corporate liability" doctrine. A landmark case adopting this doctrine is Darling v. Charleston Community Memorial Hospital. n130 In Darling, an eighteen year old broke his leg in a college football game and was taken to the defendant hospital emergency room. nl 31 The plaintiff was treated by a physician on emergency call and admitted to the hospital where he remained for several days until he was transferred to another hospital, n132 Ultimately his leg below the knee had to be amputated, n133

Plaintiff brought an action against the physician and the defendant hospital alleging that the hospital committed negligence by allowing the physician to do orthopedic work, not requiring the physician to review operative procedures, failing to adequately supervise the plaintiffs treatment, and not requiring a consultation, n134 The defendant hospital argued that as a corporation it could not [*620] practice medicine and could not control the doctor's treatment of the plaintiff, n135 The court rejected this argument holding that a hospital assumes certain responsibilities for patient care:

The conception that the hospital does not undertake to treat the patient, does not undertake to act through its doctors and nurses, but undertakes instead simply to procure them to act upon their own responsibility, no longer reflects the fact. Present-day hospitals, as their manner of operation plainly demonstrates, do far more than furnish facilities for treatment, n136

Numerous courts have followed Darling and adopted this "corporate negligence" or "corporate liability" theory, and imposed liability on hospitals for injuries resulting from the negligence of physicians on hospital medical staffs in some circumstances, n137 In Thompson v. Nason Hospital, n138 the Pennsylvania Supreme Court characterized the theory as imposing liability if a hospital "fails to uphold the proper standard of care owed its patient," and the court identified four distinct duties mandated by the standard of care:

(1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for the patients, n139

Notwithstanding the duties identified in Thompson, several courts have [*621]only discussed the theory in the context of the selection and retention of medical staff members, n140 Courts adopting the corporate liability theory emphasize that they are imposing liability on the hospital for the hospital's own negligence - not the negligence of its non-employee medical staff, n141 Nonetheless, most of the cases necessarily require proof of an underlying negligent act by a physician or other staff member whose treatment (or lack thereof) directly

contributed to the plaintiffs injury, n142 The dissent in Thompson criticized the corporate liability theory as merely a search for deep pockets and an attempt to hold hospitals "liable as guarantors of the quality of care afforded by independent staff members." n143

Professors Kenneth S. Abraham and Paul C. Weiler argue for even greater legal liability for hospitals, n144 They propose a move toward an "enterprise medical liability" system under which hospitals "would be the exclusive bearers of medical liability for all malpractice claims brought by hospitalized patients - regardless of the provider's status as employee, independent contractor, or holder of admitting privileges, and regardless of the site of the provider's malpractice." n145 A hospital's potential liability is real. As one court summarized:

Hospital governing body members have fiduciary duties as directors and under certain circumstances have exposure to personal liability. A hospital itself may be responsible for negligently failing to ensure the competency of the medical staff... by appropriately overseeing the peer review process. Hospital assets are on the line, and the hospital's governing body must remain empowered to render a final medical practice decision which could affect those assets, n146

As the Arizona Supreme Court noted, "if a patient is injured while in a hospital, regardless of who is at fault, the hospital will almost always be joined as a codefendant." n147

[*622] The current trend imposing greater liability upon hospitals for their credentialing decisions and the care provided by their medical staff members results in added pressure on hospitals to make conservative staff credentialing decisions. Hospitals, as a preventative

measure, may turn away candidates with even minor blemishes on their records or in cases where any doubt exists.

3. Economic Credentialing

In addition to quality of care and concerns about potential liability, profitability and economic considerations have also affected credentialing decisions in recent years. According to the definition of the American Medical Association, "the use of economic criteria unrelated to the quality of care or professional competency in determining an individual's qualifications for initial or continuing hospital medical staff membership or privileges" constitutes "economic credentialing." n148 For instance, a hospital may engage in economic credentialing when it decides to enter into exclusive contracts with physician groups to reduce costs, n 149 As part of these exclusive dealings, the hospital may deny privileges to other physicians practicing that specialty without regard to those physicians' competence or abilities. Furthermore, an economically-minded hospital might refuse to renew the privileges of a physician who primarily practices in other competing hospitals and does not admit a certain volume of patients to the refusing hospital. The denial of privileges because the physician has an unfavorable patient mix of private paying patients, patients on Medicare and Medicaid, and charity patients represents another example of this type of credentialing, n150

Despite the American Medical Association's strong opposition to economic credentialing, n151 hospitals who operate under substantial economic pressures [*623]have a strong incentive to consider economic factors at all levels of their operations including credentialing decisions, n152 Some reports have suggested widespread use of economic credentialing, n153 Some jurisdictions permit economic

credentialing in at least some circumstances, n154 For example, Indiana, by statute, allows consideration of "efficient and effective utilization of hospital resources" in credentialing decisions, n155 On the other hand, Illinois, to some extent, has disapproved economic credentialing. An Illinois statute states that: "the Illinois General Assembly finds: (1) That the citizens of Illinois are not served by the inappropriate use of economic criteria in determining an individual's qualifications for initial or continuing medical staff membership or privileges ..... " n156 Significantly, however, the Illinois statute only addresses "inappropriate use" of economic criteria and not any use of economic criteria and does not flatly prohibit economic credentialing. Regardless of these legal reactions, hospitals experience economic pressures and clearly want to control the cost of health care. Economic credentialing is one way to achieve this goal of cost containment. One commentator, Brian Dahl, explains:

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With the advent of cost-containment pressures brought on by diagnostic related groups (DRGs), capitated payments, and other financial risk-shifting payment schemes, hospital executives have found it increasingly necessary to exert control over physicians' use of hospital services. Although hospital executives exert no direct control over physicians' use of hospital services, hospital governing boards do exercise ultimate control over physician privileges. By tying economic considerations to a physician's privileges, the hospital's administrative staff can indirectly exert tremendous influence over service use. n157

In short, quality of care, potential legal liability, and economic factors all affect a hospital's credentialing decisions and must be considered in determining the appropriate scope of judicial review of credentialing decisions.

C. The Public's Interest

In addition to the sometimes conflicting interests of the physician and the hospital, the public's interests in physician credentialing influence judicial decision making. Above all, concern for patient health and safety properly influences court reaction to credentialing challenges, n158 This concern for public safety has resulted in a high level of deference to hospital staffing decisions. The Fifth Circuit explained:

Human lives are at stake, and the governing board must be given discretion in its selection so that it can have confidence in the competence and moral commitment of its staff. The evaluation of professional proficiency of doctors is best left to the specialized expertise of their peers, subject only to limited judicial surveillance, n159

Other facets of the public's interest in health and safety include the need for widespread availability of quality health care services n160 and the opportunity to choose a physician, n161 In the words of one court, ""both doctors and their [*625] patients can suffer if otherwise qualified doctors are wrongly denied staff privileges.'" n162

Congress and individual states have recognized the public's obvious interest in quality health care. As a result, they have enacted legislation to encourage "peer review" of physicians, n163 "Peer review" is described as "a process by which members of a hospital's medical staff review the qualifications, medical outcomes and professional conduct

of other physician members and medical staff applicants to determine whether the reviewed physicians may practice in the hospital and, if so, to determine the parameters of their practice." n164

Congress, in enacting the Health Care Quality Improvement Act expressly found that effective professional peer review would improve the quality of medical care by discouraging medical malpractice and exposing incompetent physicians, n165 To this end, Congress extended qualified immunity to physicians engaged in peer review to encourage their participation in the process, n166 States also encourage peer review as a matter of public policy, n167 For example, the Illinois Hospital Licensing Act states: "Because the candid and conscientious evaluation of clinical practices is essential to the provision of adequate hospital care, it is the policy of this State to encourage peer review by health care providers." n168

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III. Legal Theories for Judicial Review of Credentialing and Peer Review Determinations

A. The Public/Private Dichotomy

1. Constitutional Review of Public Hospital Actions

In an effort to appropriately accommodate the physician's, hospital's, and public's competing interests, courts have developed various theories and approaches applicable to claims seeking judicial review of hospital credentialing and peer review decisions. The distinction between public and private hospitals provided the basis for the first approach that emerged in the early cases. A "public"

hospital is a hospital owned, sponsored, or managed by a governmental entity -whether a federal veteran's hospital, a state university hospital, or a local community hospital, n169 In the words of several early decisions, public hospitals, like other public corporations, "are the instrumentalities of the state, founded and owned by it in the public interest, supported by public funds, and governed by managers deriving their authority from the state." n170 A "private" hospital, on the other hand, "is one that is owned, maintained and operated by a corporation or an individual without any participation on the part of any governmental agency in its control." n171

A public hospital, as an extension of the state, is subject to the limitations imposed by the United States Constitution -in particular, due process and equal protection requirements, n172 Several early decisions applied this constitutional approach holding that public hospitals could not arbitrarily or unreasonably exclude physicians from practicing in them. n173 Actions of private hospitals, on [*627] the other hand, are not subject to constitutional scrutiny, n174

This disparate treatment of public and private actors by the courts is well entrenched in our constitutional jurisprudence. In 1819, Justice Story in Trustees of Dartmouth College v. Woodward, n175 explained the distinction between public and private corporations and illustrated his point by contrasting a hospital operated as a public corporation and a hospital operated as a private corporation, n176 True to the express language of the Fourteenth Amendment, n177 the United States Supreme Court has repeatedly held that the constitutional protections of the Fourteenth Amendment apply only to state action, n178 Justice Rehnquist stated in Jackson v. Metropolitan Edison Co. n179:

In 1883, this Court in the *Civil Rights Cases, 109 U.S. 3,* affirmed the essential dichotomy set forth in that Amendment between deprivation by the State, subject to scrutiny under its provisions, and private conduct, "however discriminatory or wrongful," against which the Fourteenth Amendment offers no shield, n180

In Edmonson v. Leesville Concrete Co., nl 81 Justice Kennedy explained:

The Constitution structures the National Government, confines its actions, and, in regard to certain individual liberties and other specified matters, confines the actions of the States. With a few exceptions... constitutional guarantees of individual liberty and equal protection do not apply to the actions of private entities. This fundamental limitation on the scope of constitutional guarantees "preserves an area of [*628] individual freedom by limiting the reach of federal law." n182

Justice Kennedy continued: "One great object of the Constitution is to permit citizens to structure their private relations as they choose subject only to the constraints of statutory or decisional law." n183

Because many courts treat private hospitals with greater deference, a major issue for several decades was the determination of whether a hospital should be treated as a public or private entity, n184 Plaintiff physicians alleged constitutional protections in connection with actions of nonprofit privately owned and operated hospitals on the theory that such hospitals should be treated as public or "quasi-public" hospitals, n185 They argued that a hospital's charitable work for the public, n186 the receipt of donations from the government whether for construction of facilities or operations, n187 receipt of payments for services rendered from federal, state, or local governments under

Medicare, Medicaid, or other assistance programs, n188 liability exemptions, n189 tax exemptions, n190 and state licensing and regulation, n191 should result in a finding that such hospitals were [*629] public rather than private. The law now appears well-settled that an otherwise private hospital's actions are not state action merely by virtue of the above factors. n192

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2. Nonreview of Private Hospital Actions

Under the traditional view, private hospitals' credentialing decisions generally are subject to limited or no judicial review, n193 Some courts have referred to this rule as the "rule of nonreview." n194 In its broadest articulation the rule is:

[A] private hospital has a right to exclude any physician from practicing therein. The action of hospital authorities in refusing to appoint a physician or surgeon to its medical staff, or declining to renew an appointment that has expired, or excluding any physician or surgeon from practicing in the hospital, is not subject to judicial review. The decision of the hospital authorities in such matters is final, n195

The doctrine of nonreview developed in a string of early cases and persists in some form in numerous jurisdictions. n196

Although referred to as a rule of nonreview, this characterization and its seemingly unambiguous quality are misleading. The rule is not a complete bar to review of credentialing decisions and never was considered a complete bar; [*631]instead, the rule is a doctrine of limited review, n197 The seeds for the doctrine can be seen in an

English case dating back to 1687, where, in a single sentence decision, the court held: "[a] mandamus to restore a surgeon to an [sic] hospital was denied; because it is not in the power of the Court, nor is it a publick [sic] office." n198 In the United States, beginning in the late nineteenth century and continuing into the early twentieth century, courts held that a hospital whose business was conducted by a private corporation could impose restrictions which had the effect of excluding certain physicians, n199 The courts came to this result by applying the general corporate law doctrine that if the hospital board acted within its legitimate corporate powers and not in violation of its bylaws, the court would not interfere, n200 One early court also held that a complaining physician had no interest in the charitable trust operating a hospital and therefore had no standing to challenge the board's actions, n201

Two other cases reflecting early application of the doctrine of nonreview are Harris v. Thomas n202 and State ex rel. Wolf v. La Crosse Lutheran Hospital Ass'n. n203 In Harris, the Texas Court of Civil Appeals considered a challenge by an osteopathic doctor who was excluded from practicing in a local hospital, n204 As part of the American College of Surgeons' effort to standardize hospitals, the defendant organized its medical staff and imposed requirements for membership which excluded the plaintiff because he was an osteopath, n205 The court held that a voluntary association may determine qualifications for its membership, n206 In the court's view, membership was a privilege, and the court would not interfere with the association's decision making unless the association's rules were "against good morals or violated the laws of the state." n207 The court concluded, "we believe it to be the right of the sanitarium to refuse business relation with appellant, if it sees proper to do so." n208

[*632] In State ex rel. Wolf, n209 a hospital board without notice, hearing, or explanation, terminated a group of physicians' hospital privileges, n210 The physicians, who were until that time members of the medical staff, alleged that the hospital's actions were inconsistent with the hospital's medical staff bylaws, n211 Refusing to order a writ of mandamus requiring reinstatement of the physicians' privileges, the Wisconsin Supreme Court held that the hospital was a private corporation and its board had the power to exclude physicians from practicing in the hospital, n212 The court's holding, however, was not a general pronouncement of no review but instead was based on the requirements of mandamus. The court held out the possibility that if there were a breach of contract claim, such a claim might proceed in an action for damages or specific performance, n213

Perhaps the leading early case establishing the nonreview rule is Van Campen v. Olean General Hospital. n214 In Van Campen, a private hospital terminated a physician's staff privileges based on what the trial court found to be petty differences between the hospital management and the physician, n215 The New York court reversed the grant of an injunction in favor of the physician and found that the physician was entitled to neither notice nor a hearing, n216 The court disagreed with the lower court's determination that the hospital was a public corporation, n217 The fact that the hospital engaged in charitable work for the public, received donations and payments from the government in some cases, enjoyed protection from liability, and possessed a tax exemption, did not convert the hospital into a public corporation, n218 The court then held that it should not interfere with the internal decisions of a private corporation short of illegal or improper conduct by the board jeopardizing the corporation's property, n219

Another early case applying the nonreview rule is Strauss v. Marlboro County General Hospital. n220 In Strauss, the South Carolina Supreme Court in a brief opinion affirmed the dismissal of a claim challenging rules that excluded a physician from practicing surgery in the hospital. n221 The court held that the [*633] hospital was a private corporation. n222 The court's conclusion that the hospital was a private institution was dispositive because the parties conceded that if the hospital was private, the action would fail. n223

Other cases followed the Van Campen court, n224 In Hughes v. Good Samaritan Hospital, n225 a hospital barred a physician from performing surgeries, n226 The Kentucky Court of Appeals held that the hospital was a private institution and, in the exercise of its reasonable discretion, had the right to exclude physicians from practicing in it. n227 The court did note that the hospital had not acted for an arbitrary or capricious reason, n228

Similarly, in Levin v. Sinai Hospital of Baltimore City, n229 the Maryland Court of Appeals focused on the public/private hospital distinction in affirming the dismissal of a physician's claim against a hospital for limiting his privileges, n230 The court noted that the hospital's board had both the power to appoint and remove members of the medical staff and proclaimed that "it has never been the policy of the State of Maryland to interfere with the power of the governing body of a private hospital to select its own medical staff." n231

In Natale v. Sisters of Mercy of Council Bluffs, n232 the Iowa Supreme Court denied relief to a physician who had been a member of a private hospital medical staff for ten years but was expelled from the staff the day after he was divorced, n233 The divorce trial was reported in "dally news articles under lurid head lines [sic], and also in radio

broadcasts." n234 The physician was removed from the staff because of the "scandalous divorce case," with no charges against him, no notice, no opportunity to appear or defend himself, and no hearing, n235 In fact, he was not even given notice of his expulsion from the staff and discovered it from a lawyer friend, n236 Even given these facts, the court held that the hospital was a private hospital entitled to conduct its affairs as it saw fit. n237 The court also disregarded provisions of the medical staff bylaws affording procedural rights for expulsion from the staff, finding the bylaws were bylaws of [*634] the staff - not binding on the board, n238

3. Limitations to the Rule of Nonreview

But even these early cases recognized limits to the rule of nonreview. Van Campen noted that a court would intervene in a private hospital's internal decisions "to protect the property of a corporation... but only when corporate powers have been illegally or unconscientiously executed by the board of directors." n239 State ex rel. Wolf pointed to the possibility of a breach of contract action for damages or specific performance, n240 Levin reaffirmed a court's power to grant injunctive relief to a physician who was excluded from a hospital in violation of rights assured in the hospital's own corporate bylaws and constitution, n241 Natale qualified its holding n242 by stating that the private hospital could act as it saw fit, "as long as its acts or omissions were not fraudulent, illegal, ultra vires, intentionally, negligently, or otherwise wrongfully injurious to another. In which event it would be liable as any other private corporation, so offending." n243

A case falling within the parameters of the limitation to the rule of nonreview recognized in these cases is Stevens v. Emergency Hospital of Easton, Inc. n244 Stevens, after several years of practicing in the hospital, was denied the right to practice in the hospital, n245 Under the hospital's

constitution, the medical staff included the practitioners of medicine in good standing in the county where the hospital was located, and the hospital's bylaws added some additional qualifications, all of which Stevens satisfied, n246 Several years after the founding of the hospital, a group of physicians attempted to amend the hospital's constitution and bylaws in a manner that would allow them to exclude Stevens. n247 The court held that the amendments were ineffective because of a failure to follow the required notice procedures, and the court therefore enjoined the hospital from interfering with Steven's right to practice at the [*635]hospital. n248

As the law in this area developed, the limitation to the rule of nonreview became increasingly clear. Early cases like Van Campen, n249 Levin, n250 and Natale n251 made no distinction between denial of an initial application for privileges by one not already on the medical staff (sometimes referred to as "exclusion") and revocation, limitation, or failure to renew privileges for existing medical staff members (sometimes referred to as "expulsion"). n252 Each of those cases involved revocation or limitation of previously existing privileges, n253 Later courts, however, have adopted what some courts have characterized as an "exception" to the general rule of nonreview applicable to cases involving limitation of existing staff membership or privileges, n254 This refinement of the rule allows limited judicial review of a decision to revoke, suspend, restrict, or refuse to renew staff membership or clinical privileges in order to ensure that the hospital complied with the procedures set forth in its medical staff bylaws, and to determine whether the process afforded by the bylaws themselves afforded fair process, n255 Under this approach, a private hospital's decision to deny staff membership to a new physician applying for staff membership is not subject to [*636] judicial review, but a decision affecting a physician's existing hospital staff membership or clinical

privileges is subject to limited judicial review. This evolution of the rule is better viewed as resulting in two separate and distinct rules rather than a general rule and its exception. Characterization as a general rule and its exception is misleading because the exception - far from being the unusual or rare case - applies frequently, n256

Permitting limited judicial review in cases involving a physician's existing staff or clinical privileges may be no more than application of the limitation intimated in the early cases. A physician who enjoys a preexisting relationship with the hospital and is a member of the hospital's medical staff may have certain contractual or other rights afforded by the hospital's and medical staff's internal rules which the courts will enforce, n257 In Van Campen, the court relied in part upon the fact that no provision in the bylaws required a hearing prior to removal or suspension, n258 possibly implying a different result if the bylaws did require such a hearing, n259 Levin recognized: "In Maryland a court of equity may properly grant injunctive relief to protect a physician in his right to treat his own patients in a hospital where its constitution and by-laws accord him that right...." n260 In a 1963 case, Shulman v. Washington Hospital Center, n261 a federal district court, in dicta, also recognized the potential for review "in a case in which there is a failure to conform to procedural requirements set forth in [a hospital's] constitution, by-laws, or rules and regulations." n262

The facts in these early cases, however, did not present the issue of whether the hospitals had violated their own medical staff bylaws, and the rule of nonreview prevailed. If that issue had been presented, the dicta implies a possibly different outcome. One problem with this suggestion is the distinction between a hospital's own corporate bylaws and the bylaws of its medical staff. Many courts consider a hospital's medical staff to be a separate,

self-governing, legal entity, distinct from the hospital, n263 and the hospital and the medical staff [*637] have separate bylaws. It is unclear whether the bylaws referred to in Van Campen, n264 Levin, n265 and Shulman n266 would have included the medical staff bylaws. Furthermore, the court in Natale held that the hospital medical staff was distinct from the hospital board and that the hospital board was not bound by the provisions of the medical staff bylaws, n267

Regardless of what the early decisions may have meant, recent decisions still applying the public/private hospital distinction generally do not review challenges to initial applications, but they do allow limited review of actions affecting existing privileges, n268 At least one court refuses to review decisions affecting even existing privileges to determine compliance with bylaws, n269

Significantly, however, the limited review afforded by the rule does not foreclose statutory claims for otherwise improper conduct. For example, although a court may refuse to consider the merits of a credentialing decision, it will consider whether a decision violated a physician's civil rights or antitrust laws. n270 Vigorously adhering to the rule of nonreview, the Michigan Court of Appeals, in Long v. Chelsea Community Hospital n271 explained:

[*638]

We decline to articulate a broad principle that a private hospital's staffing decisions may never be judicially reviewed... Private hospitals do not have carte blanche to violate the public policy of our state as contained in its laws. Had plaintiff in this case asserted that defendants violated state or federal law, we may have chosen to review his claim, n272

The Pennsylvania courts have held that the substance of a private hospital's staffing decisions are not subject to judicial review where the remedy sought is an injunction to have the decision changed, but review is appropriate where the plaintiff seeks only damages under legitimate contract and tort theories, n273 The rule of nonreview, then, is a misnomer and is instead a rule of limited review.

4. Movement Away from the Public/Private Distinction

Some commentators and courts have urged abandonment of the public/private distinction and its replacement with the equivalent of constitutional due process requirements on all hospitals, public and private, n274 One commentator refers to the public/private distinction as "largely fictional" and "more historical than real." n275 Another commentator argues that the distinction between public and private hospitals "is slight" and does "not justify different judicial approaches." n276 She contends that, although private hospitals' actions may not be state action in the constitutional sense, their actions should be subject to review on state common law grounds as a result of private hospitals' exercise of "quasi-governmental authority." n277 These commentators [*639]focus on the consequences adverse actions have on physicians, patients, and the public, an effect unchanged by the hospital's status as public or private.

Of course, a focus on the immediate effect ignores the state action requirement of the Constitution. Whether a lawyer, a teacher, a secretary, or any employee's employment is terminated by a state agency or a private entity, the result to the former employee is the same - she or he has lost a job. Indeed, the private corporation may have acted without due process or arbitrarily, but, as the Supreme

Court has held, the Constitution does not provide a remedy for every private wrong, n278 Courts should not rush past fundamental constitutional requirements to obtain a result.

But the absence of a constitutional remedy does not mean there is no other basis for a remedy, and in fact many courts have moved away from the public/private hospital dichotomy, n279 Some courts rely on a contract theory, n280 Other courts use common law and public policy theories to impose more extensive judicial review, n281 Still other courts look to state statutes that impose new limits on hospitals' staffing decisions and define the scope of judicial review, n282

B. Breach of Contract - It's in the Bylaws

1. Medical Staff Bylaws are a Contract Under Majority Rule

Courts increasingly have relied on a contract theory to allow limited judicial review of hospital credentialing and peer review decisions. Under this view, medical staff bylaws constitute a contract between a physician who enjoys medical staff privileges and the hospital, n283 If the hospital takes action affecting the physician's privileges without following the procedures or requirements outlined by the bylaws, the hospital has breached its contract, n284 This theory is often cited as the basis for reviewing private hospitals' actions affecting existing privileges, n285 In the view of some courts, the theory is limited by the [*640] exclusion/expulsion distinction noted above, n286 and therefore, may not assist a physician without a current relationship with the hospital who is applying for privileges. In the view of these courts, until the physician becomes a member of the medical staff, he or she has no contractual relationship with the hospital and no contract rights under the bylaws, n287

A large majority of courts that have considered the question have held that a hospital's medical staff bylaws are a binding contract between the hospital and its medical staff members, n288 Some courts have taken a more limited position [*641land find that the medical staff bylaws alone are not a contract, but, in the context of the entire relationship between the physicians and the hospital, they are enforceable as part of a larger contractual relationship. n289 A minority of courts have declared that medical staff bylaws are not an enforceable contract, n290 Like [*642] the Iowa Supreme Court in Natale v. Sisters of Mercy of Council Bluffs, n291 a few courts have distinguished between the hospital's own bylaws and the medical staffs bylaws, holding the former contractually binding on the hospital but not the latter, n292

Two early cases adopting the view that medical staff bylaws give rise to a contractual relationship are Joseph v, Passaic Hospital Association n293 and Berberian v. Lancaster Osteopathic Hospital Association Inc. n294 In Joseph, a hospital refused to reappoint a physician to the medical staff and refused to afford him a hearing, n295 The physician complained that the hospital acted in violation of its medical staff bylaws by failing to provide him a hearing and by acting with malice, n296 The court, without analysis on the contract issue, concluded that the physician stated a cause of action "arising out of a breach of a contract between plaintiff and the hospital set out in its constitution and the by-laws of the medical staff." n297 In Berberian, a physician's medical staff privileges were terminated without notice and without opportunity for a hearing, both allegedly in violation of the medical staff bylaws, n298 The Pennsylvania Supreme Court held:

While there can be no doubt that the board of directors of the hospital has authority to deprive a physician of the privileges of the staff, it is equally clear that the board

has agreed to follow certain specified procedures before determining whether to exercise its authority in a matter of a staff member's expulsion from the hospital... When the board of directors approved the staff by-laws, they became an integral part of the contractual relation between the hospital and the members of its staff, n299

[*643] This majority view is consistent with general corporate law which holds that corporate bylaws are contracts between the corporation and its shareholders, n300

Courts finding the existence of a contract have been influenced by concern that if the bylaws were not enforceable, they would be rendered essentially meaningless, n301 One court, borrowing from Shakespeare, stated that failure to find bylaws enforceable in contract would render them merely hortatory - "much "sound and fury, signifying nothing.'" n302 On the other hand, those courts questioning whether the bylaws are a contract usually resort to the traditional elements for an enforceable contract and find one or more elements missing, n303

2. Defining a Contract

A contract broadly defined is "a promise or a set of promises for the breach of which the law gives a remedy, or the performance of which the law in some way recognizes as a duty." n304 Professor Joseph M. Perillo, in Corbin on Contracts, prefers the Uniform Commercial Code's definition of a contract: "the total legal obligation which results from the bargain of the parties in fact as found in their language or by implication from other circumstances, as affected by rules of law." n305 Neither definition, however, identifies the facts necessary for ['644]a court to find enforceable rights and duties, and both obviously call for legal conclusions about what the law will enforce.

Speaking very generally, the typical contract n306 requires: (1) parties with capacity to contract, (2) proper subject matter, (3) consideration, (4) a bargain, and (5) manifestation of mutual assent, n307 The manifestation of mutual assent may be demonstrated by an offer and acceptance, n308 The ultimate goal of the law of contracts is "the realization of reasonable expectations that have been induced by the making of a promise." n309

Concerning the requirement of parties with the capacity to contract, the possible parties to the alleged contract are the hospital, the hospital's medical staff, or both, on one side, and the physician on the other. Beyond question, the physician as an individual and the hospital as a business entity have capacity to enter contracts. The medical staff, too, as an unincorporated organization or association of physicians is capable of forming a contract with its individual ['64~] members, n310

Concerning the second requirement, the medical staff bylaws do address a lawful and proper subject matter. They identify the medical staff's purpose; set standards and procedures for admission and reappointment to the medical staff; define rights of various categories of medical staff membership; create an organizational structure; assign responsibilities within the structure; and establish procedures for corrective action, hearings, and appellate review, n311 The subject matter is not only proper but mandated by state law.

3. The Problem of Consideration

a. Consideration in the Bylaws Themselves

The other three elements - consideration, bargain, and mutual assent - have caused some difficulty in the context of medical staff bylaws. The most frequently

identified ground for finding no contract is a perceived lack of consideration. n312 A few courts reason that, because the hospital is required by state law to adopt medical staff bylaws and, in some instances, even to have a particular minimum content, the rights provided for in the bylaws cannot legally constitute valid consideration, n313 As one court explained:

The bylaws cannot be considered a contract per se because there is no mutual exchange of consideration which brought them into existence. The Hospital had the previous obligation to create those bylaws and to develop a procedure for reviewing a doctor's competency... Consequently, because the hospital had the legal duty to develop the bylaws and the procedures therein independently of its association with [the physician], no consideration could have been given for their creation, and.., without consideration, there cannot be a contract, n314

[*646] The Connecticut Supreme Court, in Gianetti v. Norwalk Hospital, n315 went a step further noting that the hospital not only had a legal duty to adopt the bylaws but also had a legal duty to abide by them. n316 According to the court, "if the department of health had not intended that the hospital abide by its medical staff bylaws, then the requirement that it enact such bylaws would be superfluous." n317 The court concluded that a hospital's agreement to abide by the bylaws could not per se constitute valid consideration, n318

Not only does state law require medical staff bylaws, but the hospital accrediting body, the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), also requires medical staff bylaws and to some extent defines their content, n319 Similarly, federal regulations governing hospitals participating in Medicare and Medicaid require adoption and enforcement of medical staff bylaws, n320 A

promise to do that which one already has a preexisting legal duty to do is not consideration, n321 Therefore, because the hospital had a preexisting legal duty to adopt and follow its medical staff bylaws, the physician received no additional benefit from the hospital's assurances or promises in the bylaws.

Consider the irony: a physician attempting to enforce the provisions of the bylaws in a contract action (whether through damages or injunctive relief) is barred because the provisions the physician is trying to enforce did not confer any added benefit to the physician. The physician cannot enforce the provisions because they were already required by law. This result turns contract law on its head because the person who allegedly received no benefit cannot enforce the agreement against the party who received benefit but purportedly gave nothing. Unfortunately, the physician has no claim under the state statutes requiring the bylaws either because the hospital did in fact have bylaws and, moreover, the statutes are regulatory in nature and typically do not confer private causes of action, n322

A fuller understanding of the preexisting legal duty contract doctrine suggests a different outcome. The purpose of this doctrine is to prevent the enforcement of promises "obtained by an express or implied threat to withhold performance of a legal duty," because such promises do "not have the [*647] presumptive social utility normally found in a bargain." n323 These concerns are not served by refusing to enforce the bylaws in a contract action. The doctrine as set forth in the Restatement (Second) of Contracts is:

Performance of a legal duty owed to a promisor which is neither doubtful nor the subject of honest dispute is not consideration; but a similar performance is consideration if it differs from what was required by the duty in a way which reflects more than a pretense of bargain, n324

Although state law, JCAHO standards, and federal regulations may require adoption of medical staff bylaws, their precise form and content are left largely to the hospital and its medical staff, n325 For example, Arizona state regulations merely require the medical staff to adopt bylaws and delineate in the bylaws eligibility requirements for medical staff membership and "state the type, purpose, composition and organization of standing committees." n326

The hospital and its medical staff, by their choice of particular procedures and methods to satisfy these legal requirements, exercise their discretion. Many of the specific provisions in the bylaws admittedly satisfy the legal requirements, but their specific details are not required. Hence, the promises may differ from what was required by the duty thereby constituting consideration. Nothing in these regulations prevents hospitals from agreeing to create rights enforceable in favor of physicians, n327 Therefore, bylaws which exceed the minimum standards required under state law satisfy the consideration requirement, n328

b. Consideration Beyond Promises in the Bylaws

Some courts look beyond the bylaws themselves to find consideration from the hospital to the physician. This approach considers all the circumstances of [*645]the hospital/physician relationship to determine whether a contract exists which includes rights under the bylaws, n329 Viewed in this way, when a hospital asks a physician to

agree in writing to be bound by the bylaws, the physician agrees, and the hospital extends privileges to the physician, an exchange of promises occurs, n330 When a physician requests privileges and a hospital extends the requested privileges, each party receives a benefit which exceeds the hospital's preexisting duty to adopt bylaws, n331 After all, the hospital has no duty to extend privileges to a particular physician, n332 With the extension of privileges, the physician is entitled to treat patients at the hospital and utilize hospital facilities; the hospital, on the other hand, receives the opportunity to provide services to the physician's patients, n333 The rights in the bylaws are then part of the hospital's commitment to the physician, n334 In the end, the consideration received by the physician to support the contract is the grant of staff privileges, n335

c. The Physician's Consideration

In Do Hospital Medical Staff Bylaws Create a Contract, n336 authors John Hulston, Donald Jones, and Timothy Gammon take a different view of consideration and argue that the physician provides no consideration to make [*649] the bylaws a binding contract:

What consideration can a... physician claim to have given, or undertaken, to make any statement in the bylaws binding as a contract? Nothing. Normally, the physician does not agree to provide a service for the hospital, does not agree to give the hospital any certain number of patients and has no contractual commitments to the hospital. Physicians should not be able to claim the hospital has any commitment to them.., n337

To the extent that this view focuses on the lack of "mutuality of obligation" n338 as a requirement distinct from consideration, n339 the approach is misguided. According to the Restatement (Second) of Contracts, "if the

requirement of consideration is met, there is no additional requirement of... mutuality of obligation." n340 It is true, however, that an illusory promise - a promise, the performance of which is entirely optional upon the promisor - is not consideration. n341 But even an illusory promise may become valid consideration when it is actually performed, n342 The employment law context provides a close analogy. Where an employer promises "job security through restrictions on the power to terminate the employment, the employee's services provide consideration for a unilateral contract." n343 Since the bylaws restrict the hospital's power to limit privileges, once the physician admits a patient to the hospital, treats patients at the hospital, or otherwise uses the hospital's facilities, [*650] the physician provides consideration through actual performance.

However, even without actual utilization of the hospital, the physician already has provided consideration. A physician is bound by any promises in the bylaws even if the physician is not required to maintain a practice at the hospital, refer any patients to the hospital, or continue an existing practice at the hospital, n344 Normally, a physician at the application stage must agree to be bound by the terms of the medical staff bylaws as a condition for staff membership n345 - regardless of whether the physician actually admits a single patient to the hospital or uses its facilities. Consideration exists because the bylaws require the physician to act in a specific way and forego certain rights.

The very fact that hospitals uniformly require physicians to agree in writing "to abide by the medical staff bylaws" n346 and to "be bound by the terms thereof" n347 is a clear indication the hospitals believe the bylaws contain promises or performance of the physicians, n348 These promises typically include: (1) grant ['651] of broad releases

and immunities from liability (with specified limitations) to the hospital, its medical staff, and others, in connection with evaluation of the application or reapplication and as part of other peer review activities; n349 (2) agreement to attend medical staff meetings; n350 (3) authorization for the hospital to consult with other medical staffs with which the applicant has been associated, and consent to inspection of records and documents necessary for the evaluation; n351 (4) a physician against whom adverse recommendation or decision has been rendered waives rights to a hearing or appellate review by failing to request them within the time limits identified in the bylaw; n352 (5) a physician may waive issues not raised during the original hearing; n353 (6) the applicant has the burden of producing information for evaluation of the application and resolving doubts about qualifications; n354 (7) the applicant has the burden of establishing his or her qualifications and competency for the clinical privileges requested; n355 (8) agreement to "strictly abide by the Principles of Medical Ethics of the American Medical Association"; n356 and (9) participate in the hospital's quality assurance programs, n357 These promises alone are consideration to support a contract, n358

Under this analysis, contract rights extend to applicants seeking staff membership as well as to those physicians who already have existing privileges. When, as part of the application process, the applicant agrees "to be bound by the terms [of the bylaws] without regard to whether or not he is granted membership and/or clinical privileges in all matters relating to consideration of his application," n359 he or she has given consideration.

d. Consideration Not Bargained For

The lack of any bargaining or negotiation between a hospital and a physician over the terms in the bylaws also influences courts that refuse to [*652] recognize the bylaws

as a contract; n360 They reason that the bylaws are not a contract is because a physician has no input in the bylaws and no power to change their terms, n361 Under the Restatement (Second) of Contracts, consideration is a performance or a return promise which "must be bargained for." n362 This bargaining requirement, however, does not require that the parties engage in actual negotiations over the terms. If that were true, any form contract would be invalid, n363 It should be sufficient that the hospital makes promises in the bylaws and promises to consider a physician's application in exchange for the physician's promise to be bound by the bylaws. This exchange of promises is then bargained for and satisfies the consideration requirement; one promise is the inducement for the other, n364 If the physician refuses to be bound, the hospital refuses to extend privileges. Likewise, if the physician disagrees with the provisions in the bylaws, the physician can walk away and not pursue staff membership there.

Furthermore, the physician who is a member of the medical staff (as contrasted with an initial applicant) actually does have the opportunity to influence the content of the medical staff bylaws. Members of the medical staff compile and adopt the bylaws, n365 Thus, individual physicians have the opportunity to vote for or against the bylaws or any changes to them. Although the hospital governing board must approve the bylaws, n366 it does not unilaterally [*653] impose the medical staff bylaws on the medical staff because both the hospital and the medical staff must approve any changes to them. n367

In Saint John's Hospital Medical Staff v. Saint John Regional Medical Center, Inc., n368 a hospital medical staff brought an action against a hospital to obtain a declaration invalidating unilaterally imposed medical staff bylaws, n369 Upon construction of the hospital in 1947, the hospital

proposed medical staff bylaws based on an existing model, n370 Both the medical staff and the hospital adopted the proposed bylaws, n371 Under the adopted bylaws, any amendments required medical staff approval by a two-thirds majority vote. n372 In 1972, the hospital attempted to make changes to the bylaws, but the medical staff refused, n373 Thereafter, the hospital unilaterally adopted new medical staff bylaws. n374 The Supreme Court of South Dakota held that the unilaterally-adopted bylaws were "null and void," and it concluded that any changes had to be approved by the medical staff in compliance with the two-thirds majority requirement in the original bylaws, n375

Some authorities appear to suggest that a hospital may unilaterally change the medical staff bylaws, n376 but these authorities must be considered in context and reviewed critically. Some of the cases may be referring to the hospital broadly, grouping together the actions of both the hospital board and the medical staff, n377 Some cases fail to distinguish hospital bylaws from medical staff bylaws, n378 merely cite unanalyzed arguments by litigants, n379 or are factually suspect in view of state law and accreditation requirements, n380 Ultimately, the [*654] bylaws are not unilaterally imposed because of both the medical staffs participation and the physician's choice to reject medical staff bylaws altogether by leaving the medical staff or declining to join. n381

e. Estoppel as a Consideration Substitute

The bylaws also should be enforceable in the absence of consideration under a theory of promissory estoppel. This theory may be invoked to enforce gratuitous promises which are not supported by consideration but which otherwise would constitute a contract, n382 The reliance element of promissory estoppel may be viewed as supplying the necessary consideration n383 or as a consideration "substitute." n384

The touchstones of promissory estoppel are reliance by the promisee and resulting hardship. The elements of promissory estoppel are often identified as: (1) a promise; (2) reliance by the promisee; (3) the reliance must be of a definite and substantial character; (4) the promisor should reasonably have anticipated the reliance; and (5) enforcement of the promise is necessary to avoid injustice, n385

The staff bylaws set forth appointment procedures, rights to notice of charges and proposed action, hearings, opportunity to present evidence, opportunity for appeal, and other rights, n386 These affirmatively stated rights [*655] should be construed as promises by the hospital to the physician, n387 After all, a reasonable physician would believe that such statements were commitments by the hospital to the physician. For example, if the bylaws state that "when any practitioner receives notice of a recommendation.., that will adversely affect his appointment to or status as a member of the medical staff.., he shall be entitled to a hearing before an ad hoc committee of the medical staff" and that "all hearings and appellate reviews shall be in accordance with the procedural safeguards set forth in this Article VIII to assure that the affected practitioner is accorded all rights to which he is entitled," n388 the physician may reasonably understand

that the hospital is making a promise, and the physician may be expected to reasonably rely upon such a promise.

The reliance is the physician's acceptance of privileges and subsequent activities as a staff member while foregoing other options. The hospital's promises of fair procedure and staff organization induce the physician to follow through with or submit his or her initial application or application for reappointment. If privileges are granted, the physician, in reliance upon those privileges, may establish a practice in the area. In a similar context, courts have discussed the reliance necessary to enforce procedural protections in employee handbooks and have held that "once an employee is aware of a policy, and his sense of job security is enhanced thereby, he need take no action in reliance on the promise except to remain on the job." n389

Finally, the potential hardship to the physician in this situation is obvious; loss of privileges may result in loss of a physician's practice and jeopardize a physician's ability to practice elsewhere, n390

4. Mutual Assent and Intent to Be Bound

A few courts have wrestled with the issue of whether the physician and hospital intended to be bound by the bylaws. n391 Without question, the physician [*656]agrees, usually in writing, to be bound by the medical staff bylaws as a condition of staff membership, n392 Whether the hospital has a corresponding intent to be bound is a closer question. In one case, Garibaldi v. Applebaum, n393 the medical staff bylaws included a provision disclaiming the creation of contractual rights, n394 The Illinois Appellate Court considered and rejected an argument that bylaws did not create contractual rights because the bylaws stated that ""these bylaws do not purport to be a contract between the Medical Staff or any of

its individual members. '" n395 Even when faced with the express provision, the court held that the bylaws created contractual rights, n396 It held that the disclaimer was against public policy and therefore unenforceable, n397

Furthermore, often the medical staff bylaws contain language that the bylaws "shall when adopted and approved be equally binding on the Board of Trustees and the Staff," n398 or that the hospital "shall be guided and governed by rules and regulations consistent with these Bylaws." n399 JCAHO, the hospitals' accrediting entity, recognizes the true essence of medical staff bylaws arising from their creation of "a system of mutual rights and responsibilities between members of the medical staff and the hospital." n400 JCAHO's standards also note that the bylaws are intended to "create a framework within which medical staff members can act with a reasonable degree of freedom and confidence." n401 In view of these requirements, state statutory mandates for the adoption of bylaws, and the accepted purposes for bylaws, courts should hold that bylaws are intended and understood to be binding on both parties.

5. Employee Handbook Analogy

Employee manuals or handbooks are sometimes considered analogous to medical staff bylaws, n402 Traditionally, courts refused to find contract rights in [*ti$7]employee manuals for many of the same reasons some courts now refuse to recognize the bylaws as a contract, n403 First, they argued that no consideration exists, and second, they pointed to an absence of mutuality of obligation, n404 In recent years, however, a large majority of courts have held that employee manuals may create an implied contract, n405 These courts usually rely on the theory of unilateral contract or promissory estoppel to resolve the consideration problem, n406 The Illinois

Supreme Court identified three requirements for enforcement of an employee manual in a contract action:

First, the language of the policy statement must contain a promise clear enough that an employee would reasonably believe that an offer has been made. Second, the statement must be disseminated to the employee in such a manner that the employee is aware of its contents and reasonably believes it to be an offer. Third, the employee must accept the offer by commencing or continuing to work after learning of the policy statement. When these conditions are present, then the employee's continued work constitutes consideration for the promises contained in the statement, and under traditional principles a valid contract is formed, n407

Based on this analysis, courts should find that medical staff bylaws create a valid contract. First, the bylaws state the promises and commitments directly and clearly, n408 Second, a physician receives copies of the bylaws and is asked to become acquainted with them. n409 Third, the physician agrees to be bound by the bylaws and accepts appointment to the medical staff if the application is [*6$$]granted. n410

In Thompson v. Saint Regis Paper Co., n411 the Washington Supreme Court held that "once an employer announces a specific policy or practice, especially in light of the fact that he expects employees to abide by the same, the employer may not treat its promises as illusory." n412 The hospital, through bylaws, announces specific policy and practices and requires physicians to comply. The hospital should not be allowed to treat its commitments as illusory, n413

6. Hospital Bylaws versus Medical Staff Bylaws

As noted earlier, a few courts have distinguished between the hospital's own bylaws and the medical staffs bylaws, holding the former contractually binding on the hospital but not the latter, n414 Under this view, the medical staff is an unincorporated association separate from the hospital itself, n415 Accordingly, it follows that the hospital as a separate party is not bound by the medical staff bylaws, n416 The bylaws would be an agreement between the medical staff collectively and individual physicians. This position, however, ignores the realities of the hospital-medical staff relationship and the essence of the medical staff bylaws.

The symbiotic relationship between the hospital and its medical staff is [*659]unique. The hospital establishes and sponsors its medical staff, n417 The hospital is required by law and for accreditation purposes to have an organized medical staff which is governed by bylaws, n418 This medical staff is a "collaborating organization" responsible to the hospital's governing board, n419 Although the medical staff adopts its own bylaws, the bylaws are not effective until approved by the hospital's board, n420 The medical staff carries out duties delegated to it by the hospital's board, n421

Under JCAHO's standards, the medical staff bylaws intentionally "create a system of mutual rights and responsibilities between members of the medical staff and the hospital." n422 In some cases, the hospital's own bylaws directly incorporate the limitations and rights afforded by the medical staff bylaws, n423 Although separate from the hospital governing board, the medical staff should be considered an arm of the hospital in the context of rights afforded to individual physicians under the medical staff bylaws, n424 Indeed many courts [*660]make no distinction

between hospital and medical staff bylaws and, instead, use the labels interchangeably or consistently refer to "hospital bylaws" when they mean the hospital's medical staff bylaws, n425

7. Consequences of Enforcing Bylaws in a Contract

Courts should hold that medical staff bylaws form a binding contract between the hospital and individual members of its medical staff. To the extent that the bylaws provide rights specific to applicants, applicants too should have enforceable contractual rights, n426 This conclusion is supported by application of contract law principles and sound policy, n427

The hospital and physician exchange promises with the intent to be bound, n428 This contract approach provides a reasonable vehicle for limited judicial review of credentialing and peer review decisions, n429

Some courts that determined the bylaws are not a contract still enforce them in an action for injunctive relief, n430 In Robles v. Humana Hospital ['661] Cartersville, n431 for example, the Northern District of Georgia reasoned that recognition of a contract would create a damage claim that would be contrary to the state's policy of allowing hospitals to choose their medical staffs, n432 But state law requirements mandating the development of bylaws and procedures to protect staff members justified judicial enforcement of the bylaws in an action for injunctive relief, n433 The district court's concern about exposing hospitals to damage claims can be addressed by qualified immunity under federal n434 and state laws n435 and specific provisions in the bylaws themselves, n436 In particular, under the federal Health Care Quality Improvement Act, hospitals which comply with certain requirements enjoy

immunity from damages for their peer review actions, n437 This immunity covers damage claims for breach of contract, including alleged breach of the bylaws, n438 If the immunity provisions do not apply because of the presence of such factors as bad faith, n439 damage claims may be warranted [*662] and necessary to make the physician whole.

A finding that the bylaws are an enforceable contract is not a one way street favoring physicians - hospitals too stand to benefit, particularly from waiver and immunity provisions, n440 In Brinton v. IHC Hospitals, Inc., n441 the Utah Supreme Court held that the express waiver provision of the bylaws bound a physician who therefore had a duty "to take affirmative steps to raise issues in a timely fashion." n442 The physician was "contractually bound to raise any objections during the [peer review] process or relinquish them as waived." n443 Accordingly, alleged procedural violations which the physician failed to raise in his peer review hearings and before the hospital board could not support a cause of action, n444

In Everett v. Saint Ansgar Hospital, n445 the Eighth Circuit enforced an immunity provision and held that a physician's breach of contract claim for suspension and revocation of his privileges was waived, n446 It held:

Even if there was such a violation, however, [the physician] waived his right to sue for a breach of the contract. When he applied for hospital privileges, [the physician] specifically acknowledged that with respect to actions taken for the purpose of achieving and maintaining an acceptable level of patient care "there shall, to the fullest extent permitted by law, be absolute immunity from civil

liability arising from any such act... Such immunity shall apply to all acts... performed or made in connection with this.., health care institution["s] activities related.., to... corrective action." n447

C. Common Law Review: Fiduciary Duty and Fairness

1. New Jersey's Fiduciary Duty Theory

A number of courts have rejected both the public/private distinction and [*663]breach of contract analysis in favor of allowing judicial review of credentialing and peer review decisions based on public policy grounds. These courts recognize a hospital's fiduciary duty, benefiting the public, to make reasonable peer review and credentialing decisions. The New Jersey Supreme Court first recognized this theory in Greisman v. Newcomb Hospital, n448 which serves as the foundation for one public policy theory alternative.

In Greisman, the plaintiff, a graduate of a school of osteopathy, applied for staff privileges at a private hospital, n449 The hospital refused to accept plaintiffs application for admission to the staff because the bylaws required staff members to be graduates of an American Medical Association approved medical school, and this requirement excluded all schools of osteopathy, n450 The hospital first argued that as a purely private hospital its staffing decisions were not subject to judicial review, n451 The court rejected this argument, n452 It questioned the private nature of hospitals generally and the defendant hospital in particular:

[Private hospitals] are private in the sense that they are nongovernmental but they are hardly private in other senses. [The defendant hospital] is a nonprofit organization dedicated by its certificate of incorporation to the vital

public use of serving the sick and injured, its funds are in good measure received from public sources and through public solicitation, and its tax benefits are received because of its nonprofit and nonprivate aspects. It constitutes a virtual monopoly in the area in which it functions and it is in no position to claim immunity from public supervision and control because of its allegedly private nature, n453

The court compared hospitals to other private businesses that have special common law duties, n454 For example, private innkeepers and common carders have a duty to serve "all comers on reasonable terms," and private railroad companies "hold their property "as a quasi-public trust.'" n455 The court also relied on its own earlier precedent striking down a private, nonprofit county medical society's arbitrary membership requirement, n456 The court found that the hospital was dedicated to serve the public and was the only hospital in the area. "Hospitals are operated not for private ends but for the benefit of the public, and.., their existence is for the purpose of faithfully furnishing facilities to the members of the medical profession in aid of their service to the public." n457 The court concluded that the hospital's power to pass on staff membership applications is a fiduciary power held in trust which must be exercised [*664] reasonably for the public good. n458

Under this public policy approach, the judicial inquiry may be more probing than merely ensuring the hospital's compliance with procedures in the bylaws. Instead, the court asks whether the hospital has acted in accordance with its fiduciary duty, and "a court should not hesitate in promoting natural justice to fill any gaps" in "self-serving" bylaws. n459 Indeed in Greisman, the issue was not whether the hospital complied with its bylaws, but whether the bylaws themselves were reasonable, n460 The result of the holding in Greisman, and cases like it, has been the

imposition of an arbitrary, capricious, or unreasonable standard on all hospitals, whether public or private, in connection with their credentialing and peer review decisions, n461 In the words of one court: "The better rule provides that such review be available as to whether the doctor excluded was afforded procedural due process, and as to whether an abuse of discretion by the hospital board occurred, resulting in an arbitrary, capricious or unreasonable exclusion." n462 Several states have followed Greisman's lead. n463 [*665] Although Greisman involved a physician applying for admission to the medical staff, its holding also has been applied to cases involving the revocation or limitation of privileges, n464

These courts suggest that a hospital's credentialing decisions result from the exercise of "fiduciary powers," powers held "in trust," n465 and that the hospital "occupies a fiduciary trust relationship between itself, its staff and the public it seeks to serve." n466 A fiduciary relationship, however, should not be found to exist between the hospital, its physicians, as well as the public. The Restatement (Second) of Torts defines a fiduciary relationship as a relationship "between two persons when one of them is under a duty to act for or to give advice for the benefit of another upon matters within the scope of the relation." n467 A fiduciary relationship in the hospital credentialing context does not fit well with the traditional categories of fiduciaries. One authority identified the following typical fiduciary categories:

An attorney is a fiduciary for a client, a corporate director or officer for the corporation or its shareholders, a promoter for the corporation, an agent for the principal, a guardian for the ward, joint venturers for one another, a partner for the other partners, a bailee for the bailor, a securities broker for a customer, a member of a creditor's committee for the creditors, and, in class action lawsuits, the

representative of a class for its members. According to some authorities, a physician or a psychiatrist may be a fiduciary for a patient, an employee for his employer, a stockholder for the other stockholders in a closely held corporation, and a priest for a penitent, n468

The courts should not find a fiduciary relationship between a hospital and a physician excluded or expelled from the hospital's medical staff. The hospital, in [*666] its staffing decisions, acts in its own interests and does not purport to act primarily in the interest of the applicant, n469 Indeed, the physician is the subject of the hospital's scrutiny during the process.

A closer question is whether a fiduciary relationship might exist between a hospital and the public. In short, does the hospital in making credentialing decisions consider primarily its own interests or the interests of the public? n470 In one sense, the public does rely upon hospitals to make staffing decisions and to police the quality of their staff membership. But the public does not entrust hospitals with any confidential information or property, nor does the hospital make decisions on behalf of the public, n471 A hospital's credentialing decisions are made based on the interests of the hospital itself. This self interest is particularly strong in the actions of private for-profit hospitals who, like other for-profit businesses, presumably have their own economic interests foremost in mind. Of course, the hospital's own interests often coincide with the public's interests. But hospital provision of health care services, although unquestionably important to the public, does not make private hospitals fiduciaries to the public, n472 As flexible as the theory of fiduciary duties is, it should not stretch to cover a private hospital's relationship with the general public or physicians applying for privileges.

Assuming a hospital has fiduciary duties to the public, those duties are not implicated by exclusion of a physician from a hospital's medical staff. Any fiduciary duty does not require that a hospital accept into its membership every qualified physician. Exclusion of a physician does not make the existing medical staff less safe or endanger the public. The hospital has not misused any property of the public or any confidential information entrusted to it by the public. The public has not been misled or deceived. Even if the public is wronged, n473 any liability for the breach would be to the public - not to an offended physician to whom no duty was owed. n474

2. California's Common Law Fair Procedure Theory

The California courts, building on their own precedents and citing Greisman [*667]and its progeny, n475 also have rejected the public/private hospital distinction and a contractual approach, and allow review of hospital credentialing decisions based on the "common law right of fair procedure." n476 The California Supreme Court in Antonv. San Antonio Community Hospital n477 stated the rule "that a physician may neither be refused admission to, nor expelled from, the staff of a hospital, whether public or private, in the absence of a procedure comporting with the minimum common law requirements of procedural due process." n478 Other California decisions have made clear that the right afforded is not constitutional due process, but a common law right of fair procedure, though the distinction is of little consequence, n479 The right of fair procedure is flexible, but at a minimum [*668] it requires "adequate notice of charges, a reasonable opportunity to respond, and an impartial tribunal" if a hearing is required, n480 Moreover, review is not limited to procedural fairness;

it also allows scrutiny of substantive requirements to determine whether a requirement is "irrational, unlawful or contrary to established public policy." n481

Although the California courts partially erased the public/private hospital distinction by applying procedural due process to public hospitals and common law fair procedure to private hospitals - in substance the same standard n482 -the distinction remained significant as a result of legislation overruling in part the 1977 Antonv. San Antonio Community Hospital n483 decision. The Anton decision required courts to exercise their "independent judgment" in reviewing the factual basis for a hospital board's decision, n484 In 1978, the legislature amended California's mandamus statute, which is the mechanism for seeking injunctive relief from hospital decisions, n485 to specifically limit the courts' scope of review of private hospital board decisions to a substantial evidence standard, n486 This alteration in the mandamus proceedings is significant not only for a claim for injunctive relief, but also for damage claims since a physician cannot seek damages until after a successful mandamus action, n487 Under the substantial evidence standard, the courts ""review the administrative record to determine whether its findings are supported by substantial evidence in the light of the whole record,'" and will uphold the findings "unless [they] are so lacking in evidentiary support as to render them unreasonable." n488 While substantial evidence is the standard of review for factual findings, the courts continue to [*669] conduct an independent review to determine whether fair procedure was afforded, n489 The public/private hospital distinction appears to have receded again with a 1992 amendment to section 1094.5(d), applying the substantial evidence standard to decisions of both private and municipal hospitals, n490

Under California law, a physician whose privileges are denied or withdrawn, before bringing a damage action, must first exhaust the hospital's administrative process in addition to prevailing in a mandamus action to overturn the hospital decision, n491

3. Other Courts' Public Policy Review

Many courts that continue to adhere to the public/private distinction and rely on a breach of contract theory also engage to some degree in a common law public policy judicial review. West Virginia's highest court, expressly relying on breach of contract principles, sets forth this approach:

... the decision of a private hospital to revoke, suspend, restrict or to refuse to renew the staff appointment or clinical privileges of a medical staff member is subject to limited judicial review to ensure that there was substantial compliance with the hospital's medical staff bylaws governing such a decision, as well as to ensure that the medical staff bylaws afford basic notice and fair heating procedures, including an impartial tribunal, n492

These courts look beyond merely whether the bylaws were followed; they also consider whether the bylaws themselves afford due process, n493 The West [*670]Virginia court continued, "there are basic, common-law procedural protections which must be accorded a medical staff member by a private hospital in a disciplinary proceeding which could seriously affect his or her ability to practice medicine." n494 In addition, the Illinois Supreme Court explained: "A court, however, will be justified in reviewing a private hospital's actions even where the bylaws are followed if actual unfairness.., is demonstrated in the record." n495

D. State Statutes Define the Scope of Judicial Review

In addition to judicial review based on theories of constitutional due process, contractual rights, or common law fair procedure, state legislatures have addressed the scope of judicial review of hospital peer review decisions. State statutes vary widely, but they generally function in four ways.

1. Statutes Granting Immunity from Damages

Nearly all states have statutes which grant immunity from damages to individuals and entities involved in peer review proceedings in certain circumstances, n496 These provisions provide a qualified immunity from damages for actions taken in good faith, without malice, or under some other standard. An example of such an immunity statute is the Florida statute which provides:

There shall be no monetary liability on the part of, and no cause of action for damages against, any licensed facility, its governing board or governing board members, peer review panel, medical staff, or disciplinary body, or its agents, investigators, witnesses, or employees; a committee of a hospital; or any other person, for any action taken without intentional fraud in carrying out the provisions of this section [i.e. peer review], n497

These immunity statutes are not uniform. Some apply to individuals involved in the peer review process but not to hospitals, n498 Among those statutes which do apply to hospitals, the standards differ. The statutes either adopt an [*671] absolute immunity from damages standard, n499 a

"good faith" standard, n500 a "without malice" standard, n501 or some other standard, n502 Courts have applied these various immunity statutes to dismiss damage claims brought by physicians in numerous cases, n503

2. Statutes Requiring Specific Admissions Criteria, Peer Review Standards, or Due Process Requirements

Some statutes require hospitals to adopt specific admissions criteria, peer review standards, and procedural due process rights either in bylaws or other hospital regulations, n504 These statutory requirements in some instances are detailed, n505 and in others instances general and brief, n506 These requirements may [*672] provide the legal basis for challenges to hospital action and conversely limit a court's review, n507

New York is an example of a state which has adopted such a statute. New York for many years followed the traditional rule of nonreview of private hospital staffing decisions announced in Van Campen v. Olean General Hospital, n508 holding that "denial of staff privileges, for whatever reason or for no reason at all, constituted no legal wrong." n509 In 1972, however, the legislature modified the common law by enacting section 2801-b of the Public Health Law which states in relevant part:

It shall be an improper practice for the governing body of a hospital to refuse to act upon an application for staff membership or professional privileges or to deny or withhold from a physician.., staff membership or professional privileges in a hospital, or to exclude or expel a physician.., from staff membership in a hospital or curtail, terminate or diminish in any way a physician's.., professional privileges in a hospital, without stating the reasons therefor, or if the reasons stated are unrelated to

standards of patient care, patient welfare, the objectives of the institution or the character or competency of the applicant, n510

A physician alleging violations of this provision, after exhausting the administrative remedies outlined in the statute, may seek an injunction to enforce the provision, n511

[*673] Similarly, Florida initially distinguished between public and private hospitals and followed the rule of nonreview, n512 The Florida legislature in 1975, however, enacted a statute imposing duties on hospitals in connection with their staff membership and peer review decisions, n513 The statute in effect eliminates the public/private hospital distinction as it related to protecting staff privileges and sets forth valid criteria for evaluation of membership application and for limiting existing privileges, n514 These statutory provisions provide the basis for claims by physicians for injunctive relief and potential damages, n515

3. Statutes Specifically Addressing the Process for Judicial Review and Standards to Be Applied

Several statutes expressly identify the process for judicial review of an adverse decision or the standards the courts should apply, n516 A Virginia statute [*674] requires a hospital to provide a physician, in writing, the reasons for denial or termination of privileges, n517 The statute also identifies several impermissible reasons for a denial or termination of privileges, n518 If a hospital violates the statute's requirements, a physician has the right to seek an injunction prohibiting any further violation from the circuit court, n519 An Arizona statute specifically allows "an action for injunctive relief seeking to correct [a hospital's] erroneous decision or procedure." n520 The Arizona statute also determines the court's standard of review: "If the record

shows that the denial, revocation, limitation or suspension of membership or privileges is supported by substantial evidence, no injunction shall issue." n521

The California mandamus statute provides for review of hospital credentialing decisions in the reviewable category of "any final administrative order or decision," and it specifically adopts an abuse of discretion standard for review of hospital decisions, n522 Abuse of discretion is shown if "the findings are not supported by substantial evidence in the light of the whole record." n523 The California statute further identifies the standard necessary to stay the hospital decision while the action is pending, n524 A District of Columbia statute lists a number of factors which may not support an adverse credentialing determination, but it does permit an action in the District's Superior Court to enjoin violations of the statute, n525 Moreover, in a challenge to the hospital's determination, the hospital has the burden to establish that it did not rely on an improper factor, n526 The Colorado and New York statutes specifically permit judicial review following consideration by special administrative boards, n527

4. Statutes Creating Administrative Review

Finally, a statute may create an administrative review board to hear the merits of a physician's claim prior to any court action. Both New York and Colorado have taken this approach, n528 The New York statute permits a court to order injunctive relief against a hospital in accordance with the process identified ['675]in the statute, n529 First, an aggrieved physician must submit a complaint to the New York Public Health Council ("PHC") who investigates the complaint, n530 After its investigation, the PHC may direct the hospital to reconsider its decision or announce its own finding that the complaint lacks merit, n531 Following the PHC review, the physician may then

commence a court action for injunctive relief or damages, n532 The statutory scheme permits the PHC, a body with expertise in the health care field, to consider the merits of the hospital's action before any judicial involvement. This body plays an important mediation role by offering both the physician and the hospital a qualified independent opinion based on the facts. The New York Court of Appeals has observed that "under the conciliating professional influence of the PHC - an impartial third party with vast experience and unparalleled expertise in these cases - disputes between physician and hospital may be resolved expeditiously avoiding costly and protracted litigation." n533 The PHC also plays a fact finding role which will assist in any future litigation on the matter, n534 Under the statute, the PHC's findings of fact are prima facie -though not conclusive - evidence of the facts found in any subsequent judicial proceeding, n535

Similarly, Colorado, by statute, has established the Committee on Anticompetitive Conduct (the "Committee") which reviews claims of unreasonable anticompetitive conduct made by physicians in connection with their privileges or staff membership, n536 The Committee consists of five members, four of whom must be licensed to practice medicine and actively practicing medicine, n537 The statute provides, in relevant part:

Any physician who is the subject of a final action by a governing board, which action results in the denial, termination, or restriction of privileges at or membership in or participation in an organization, and who believes that such action resulted from unreasonable anticompetitive conduct shall have, as his sole and exclusive remedy, [*676] direct review of the record by the committee. Such review shall be limited to the sole issue of whether such final board action resulted from unreasonable anticompetitive conduct. Failure to exhaust this administrative remedy before the

committee shall preclude the right of de novo review on the merits of the issue of unreasonable anticompetitive conduct, n538

The procedure before the Committee is noted in the statute. Ultimately, the Committee may (1) set aside or modify the hospital's action, (2) dismiss the complaint, or (3) remand the case to the hospital board for further review, n539 Following the Committee's review, the action of the Committee may be reviewed by the state's court of appeals, or the action of the hospital may be reviewed de novo on the merits in a district court, n540 Claims not alleging anticompetitive conduct may be raised directly with the court, n541

E. Substantial Compliance with the Bylaws and Abuse of Discretion

If a court decides that review is appropriate, it must determine what level of review it will allow. Courts overwhelmingly agree that a hospital's determination is entitled to great deference, n542 Hospitals exercise their expertise in making staffing decisions, n543 Courts, therefore, are and should be reluctant to second guess those decisions.

Courts that review hospital decisions for compliance with the bylaws almost uniformly apply a substantial compliance standard, n544 Some courts limit review [*677] to compliance with procedural requirements in the bylaws but will not consider the merits of any underlying medical decision, n545 Under this approach, the court will only consider, for example, whether the physician received appropriate notice, had an opportunity to respond to the charges, and whether the process was otherwise fair. n546 Other courts will review the basis for the hospital's decision under either an abuse of discretion, substantial evidence, or

arbitrary and capricious standard, n547 This limited review of the substantive evidence is viewed by some as merely an integral part of the procedural review because "such examination is in recognition that an inherent element of fair hearing procedures is that there be sufficient evidence to support the hospital's decision." n548

Conclusion

Judicial review of credentialing decisions presents difficult questions for physicians, hospitals, and the courts. The courts, using various theories, attempt to balance the competing interests of the physician, hospital, and public, n549 The seeming complexity and variety of approaches found in the cases - characterized by one commentator as a "dismal swamp" n550 - at times is daunting. Nonetheless, [*678] the outcomes of the cases are more uniform than one might expect, n551 In the final analysis, regardless of the underlying theory, most courts review decisions expelling physicians from medical staffs or limiting their privileges to ensure that the physician was afforded what amounts to procedural due process. That due process review for decisions of public hospitals is grounded, at least as a minimum, on constitutional protections, n552 For private hospitals, the due process review is based on contract (the bylaws), fiduciary duty, common law fairness, or statute, n553

In contrast to decisions affecting existing privileges, the courts are sharply split on the question of review of private hospital decisions excluding physicians from medical staffs, n554 Many courts follow the rule of nonreview, but many other courts allow review under fiduciary duty, common law fairness, or statutory theories, n555 Courts are uniformly reluctant to delve into the substantive merits of a physician's claim, n556 However, many courts do venture beyond purely procedural issues

and will consider whether the decision was based on substantial evidence or was not arbitrary or capricious, n557

Most courts will permit injunctive relief to an aggrieved physician, n558 Claims for damages, however, are difficult to maintain and rarely successful. Federal and state immunity statutes, coupled with the considerable deference courts give hospital staffing decisions, n559 set a very high, and in most cases insurmountable, standard. The courts are correct in exercising caution when reviewing hospital staffing determination. They should avoid creating a situation where they are required to make determinations concerning the appropriateness of care or a particular physician's abilities. Hospitals generally, and private hospitals in particular, should be afforded great deference in their internal staffing decisions. Private hospitals, like other private entities, should be permitted to decide who meets their particular standards and needs without judicial second guessing or, as one judge put it, "Monday-morning quarterbacking." n560 Our jurisprudence and governmental system demand respect for the diversity and autonomy of private entities. Judicial intrusion on [*679] common law or public policy grounds without statutory guidance should be minimized. A court may decide a case and never consider the matter again, but a hospital, its staff, and its patients must live with the consequences. Reinstating a physician or merely discouraging a hospital from taking action against a physician because of fear of lengthy and difficult legal proceedings have long-term consequences for both the hospital and the public. Most importantly, public safety may be compromised.

Courts should find that the hospital and medical staff bylaws are contractually binding in favor of both applicants and medical staff members. The elements of a contract are satisfied, n561 and contract law provides a valid, principled basis for judicial review of credentialing

and peer review decisions. Specific statutory provisions also provide a valid basis for judicial review and in some jurisdictions provide a helpful mechanism for administrative review and dispute resolution prior to judicial review. Under these theories, a court can and should determine whether fair procedures were provided to a physician including: notice of the proposed action, notice of the grounds for the proposed action, notice of rights afforded by the bylaws and other regulations, notice of hearings which the physician is entitled to attend, adequate opportunity to prepare a response, opportunity to respond, opportunity to present evidence, a hearing before an unbiased panel, opportunity for appeal, and notice of right to appeal. The court's review should also include consideration of whether the hospital's decision was based on a proper purpose as defined by the bylaws or state law. If the procedures in the bylaws were followed, the hospital's decision should only be overturned if the court finds that the hospital acted arbitrarily and capriciously and contrary to the substantive standards imposed by the bylaws or state law.

FOOTNOTES:

n1. See Joint Commission on Accreditation of Healthcare Organizations, Comprehensive Accreditation Manual for Hospitals: The Official Handbook MS-7 (1999) [hereinafter "JCAHO Manual"] (defining and discussing the credentialing process). See also infra notes 69-88 and accompanying text for a discussion of the credentialing process.

n2. See Susan O. Scheutzow, State Medical Peer Review: High Cost But No Benefit - Is it Time for a Change?, *25 Am. J.L. & Med. 7 (1999)* (defining peer review); Arthur F. Southwick & Debora A. Slee, Quality Assurance in Health Care: Confidentiality of Information and Immunity for

Participants, 5 J. *Legal Med. 343, 344 (1984)* (stating that credentialing process is only one facet of peer review, the broader concept including utilization review, infections review, and review of specific hospital functions).

n3. See generally JCAHO Manual, supra note 1, MS.5 to MS.5.11 at MS 7-10 (discussing application process and requirements). See also infra notes 73-83 and accompanying text for a discussion of the application process.

n4. See JCAHO Manual, supra note 1, MS.5.4, MS.5.4.3 at MS-8 (discussing consideration of professional criteria).

n5. See id. MS.5.11, at MS-10 ("Appointment or reappointment to the medical staff and the granting, renewal, or revision of clinical privileges are made for a period of no more than two years."). See also infra notes 84-86 and accompanying text for a discussion of the reappointment process.

n6. See infra notes 86-88 and accompanying text for a discussion of possible adverse actions.

n7. See infra notes 89-112 and accompanying text for a discussion of the impact of an adverse action.

n8. See Timothy Stoltzfus Jost, The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest, *24 B.C. L Rev. 835, 846 (1983)* (discussing function of hospitals in various periods); Paul Starr, The Social Transformation of American Medicine 147-54 (1949) (discussing nature of hospitals prior to twentieth century). See also, e.g., *Schloendorff v. Society of N. Y. Hosp., 105 N.E. 92, 92 (N. Y. 1914)* (noting charitable nature of New York hospital first formed in 1771). For a discussion of the history of hospitals generally, and the founding and

evolution of the first American hospitals, see Malcolm T. MacEachern, Hospital Organization and Management 1-28 (3d ed. 1957).

n9. See Jost, supra note 8, at 848-49 (noting that percentage of hospitals with organized staffs increased dramatically between 1918 and 1935); Milton I. Roemer & Jay W. Friedman, Doctors in Hospitals: Medical Staff Organization and Hospital Performance 34-36 (1971) (noting lack of systematic policy in early hospitals).

n10. Gary S. Belkin, The Technocratic Wish: Making Sense and Finding Power in the "Managed" Medical Marketplace, 22 J. Health Pol. Pol'y & L. 509, 524 (1997) (quoting John G. Bowman, Standardization of Hospitals (1918)).

n11. Loyal Davis, Fellowship of Surgeons: A History of the American College of Surgeons 63 (American College of Surgeons ed., 1973) (1960).

n12. See Eleanor D. Kinney, Private Accreditation as a Substitute for Direct Government Regulation in Public Health Insurance Programs: When is it Appropriate?, 57 Law & Contemp. Probs. 47, 50 (Autumn 1994) ("Until the twentieth century, most health care was provided at home."); Morris J. Vogel, The Transformation of the American Hospital, 1850-1920, in Health Care in America: Essays in Social History 105, 105-06 (Susan Reverby & David Rosner eds., 1979) (stating "even the most difficult surgical procedures were preformed in the home, often in the kitchen").

n13. Starr, supra note 8, at 162. See also, id. at 162 (stating 1907 survey in the Bronx and Manhattan revealed that only about ten percent of physicians had hospital privileges).

n14. See Vogel, supra note 12, at 105 (stating "even the most difficult surgical procedures were performed in the home, often in the kitchen").

n15. See Tom Vitelli, The Story of Intermountain Health Care 15 (1995) (noting popular bias against hospital care).

n16. Starr, supra note 8, at 157.

n17. See Davis, supra note 11, at 62-63 (attributing expansion to growing volume of surgical work); Starr, supra note 8, at 156-57 (same).

n18. See Kinney, supra note 12, at 50. See also Rosemary Stevens, In Sickness and in Wealth: American Hospitals in the Twentieth Century 17 (1989) (discussing the role of hospitals in early twentieth century).

n19. Starr, supra note 8, at 146.

n20. Id.

n21. Id. at 163-64 (stating "rule forbidding physicians to take fees from private patients [in hospitals].., began to die out at the turn of the century"); Stevens, supra note 18, at 30-39 (discussing income from paying patients to nonproprietary hospitals). The shift from charity care to paid services resulted from several factors including the increased cost of hospital services and the increased demand for hospital services. By the early 1900s, a "general crisis in hospital finance had become [ ] widely recognized," and "many facilities began to look toward pay patients as a new source of income." David Rosner, Business at the Bedside: Health Care in Brooklyn, 1890-1915, in Health Care in America: Essays in Social History 117, 121-22 (Susan Reverby & David Rosner eds., 1979).

n22. Roemer & Friedman, supra note 9, at 35. See also Starr, supra note 8, at 163 (noting hospital appointments became more valuable as hospitals became "indispensable for surgical practice and specialization"); id. at 167 (stating that by 1933 only one in six physicians was not affiliated with hospital).

n23. See Jost, supra note 8, at 846 (noting growth in number of hospitals); Bureau of the Census, Historical Statistics of the United States 35 (Robert Burgess, Director 1957). MacEachern puts the 1873 figure at 149 hospitals. MacEachern, supra note 8, at 21. Using a measure of hospital beds per thousand population, the numbers went from 4.7 in 1909 to 7.8 in 1930. See Bureau of the Census, Historical Statistics of the United States 35 (Robert Burgess, Director 1957) (statistic not kept prior to 1909).

n24. See Roemer & Friedman, supra note 9, at 35 (outlining requirements for professional membership in ACS); Jost, supra note 8, at 847 (detailing history of ACS). The ACS was incorporated in 1912, and its first organizational meeting occurred in 1913. Davis, supra note 11, at 70-71, 91.

n25. Davis, supra note 11, at 63, 70.

n26. See Memorandum from JCAHO, Joint Commission History (JCAHO 1/99) (fact sheet available from JCAHO). See Davis, supra note 11, at 204-29 for a discussion of the origins of the ACS and the hospital standardization program,

n27. See Jost, supra note 8, at 848 ("The HSP sought regularly to analyze and audit hospital progress toward compliance with the minimum HSP standards. Like the earlier ACS standards, HSP standards focused on the organization and suitability of the hospitals for physicians.")

(footnote omitted); id. at 848 ("By 1941, the minimum standard had been supplemented by sixteen additional standards....").

n28. The ACS continued its program of voluntary hospital accreditation until 1952 when it officially transferred the HSP to the Joint Commission on Accreditation of Hospitals ("JCAH"). See *Woe v. Cuomo, 559 F. Supp. 1158, 1163 (E.D.N.Y. 1983),* (citing information located in JCAH twenty-fifth anniversary brochure), affd in part, rev'd in part, *729 Fo2d 96 (2d Cir. 1984);* Joint Commission History, supra note 26 (JCAHO 1/99). The ACS, the American Hospital Association, the American Medical Association, the American College of Physicians, and the Canadian Medical Association created the JCAH in 1951. See Joint Commission History, supra note 26 (JCAHO 1/99); Jost, supra note 8, at 851 (providing history of JCAH). In 1987, JCAH changed its name to the Joint Commission on Accreditation of Healthcare Organizations. See Joint Commission History, supra note 26 (JCAHO 1/99) (outlining history of JCAH); Kinney, supra note 12, at 52 n.25 (detailing history of JCAHO).

n29. See MacEachern, supra note 8, at 669-70 (reproducing Minimum Standard).

n30. Id.

n31. See Jost, supra note 8, at 848-49 (discussing effect of ACS standardization efforts). Several cases from the period indicate that many hospitals organized their medical staffs directly in response to the ACS's efforts. See *Newton v. Bd. of Comm'rs, 282 P. 1068, 1069 (Colo. 1929)* (referring to efforts to conform to ACS requirements of hospital standardization concerning privileges to practice in hospital); *State ex rel. Wolf v. La Crosse Lutheran Hosp. Ass'n, 193 N.W. 994, 994 (Wis. 1923)* (stating that hospital in 1919,

"in conformity with the movement initiated by the American College of Surgeons to standardize hospital service" created "the attending staff"); *Harris v. Thomas, 217 S.W. 1068, 1072-74 (Tex. Civ. App. 1920)* (noting that hospital organized medical staff in 1919 as part of larger movement promoted by ACS, American Medical Association and Catholic Hospital Association). But cf. *Lambing v. Bd. of Comm'rs, 263 P. 992, 992 (Idaho 1928)* (noting enactment and then repeal of resolution that hospital should be standardized in accordance with minimum requirements of ACS and form medical staff).

n32. See Jost, supra note 8, at 847 (explaining term "open staff"); Roemer & Friedman, supra note 9, at 34, 36 (noting typical late nineteenth/early twentieth century American hospital was "open staff"); cf. id. at 37 (noting appeals in 1912-1920 literature that medical staff appointments be merit based rather than based on social or political connections or no standards at all).

n33. Stevens, supra note 18, at 53.

n34. Id. at 53. See also id. at 78, 116-17 (discussing impact of national rules on hospitals).

n35. MacEachern, supra note 8, at iv (quoting Minimum Standard II).

n36. *Harris v. Thomas, 217 S. W. 1068, 1072 (Tex. Civ. App. 1920).* In Harris, the hospital's standardization plan "contemplated that the members of said staff shall meet at regular intervals, criticize their practice, and eliminate from their members such as may prove to be incompetent and unfit, the plan likewise contemplated finally specialized work as a basis for competency and fitness." *Id. at 1072.*

n37. JCAHO Manual, supra note 1, MS. 1, at MS-2.

n38. Id. at MS-1 to MS-92.

n39. See Jost, supra note 8, at 845 (stating that eighty percent of all acute care hospitals and "virtually all hospitals with more than twenty-five beds" are JCAH [now JCAHO] accredited).

n40. See Timothy Stoltzfus Jost, Medicare and the Joint Commission on Accreditation of Healthcare Organizations: A Healthy Relationship?, 57 Law & Contemp. Probs. 15, 21 (Autumn 1994) (noting that states rely extensively on Joint Commission Accreditation). See also, e.g., 12 Va. Admin Code 5-410-210 (West, WESTLAW through Aug. 14, 2000) (creating presumption that hospital accredited by JCAHO and with Medicare certification meets licensing requirements).

n41. See, e.g., Ariz. Admin. Code R9-10-214(A) (West, WESTLAW through Dec. 31, 1999) (requiring Arizona hospitals to have organized medical staff); Fla. Admin. Code Ann. r. 59A-3.220(1) (West, WESTLAW through July 1, 2000) (mandating that each hospital have organized medical staff); Kan. Admin. Regs. 28-34-6a(a) (West, WESTLAW through Jan. 1, 1999) (requiring hospitals to have organized medical staff); 12 Va. Admin. Code 5-410-210 (West, WESTLAW through Aug. 14, 2000) (stating that each hospital must have organized medical staff "responsible to the [hospital] governing body" and whose bylaws are approved by the hospital's governing body). Federal regulations require hospitals participating in Medicare and Medicaid to have organized medical staffs. See, e.g., *42 C.F.R. 482.22* (1999) ("The hospital must have an organized medical staff that operates under bylaws

approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.").

n42. JCAHO Manual, supra note 1, MS. 1.1.1, at MS-2.

n43. See id. MS.6.2, at MS- 11 (defining "qualified physician" to include doctors of medicine and doctors of osteopathy).

n44. See, e.g., *Illinois Psychological Ass'n v. Falk, 638 F. Supp. 876, 880 (N.D. Ill. 1986)* (noting psychologists were serving on medical staffs at several Chicago-area hospitals, but considering department of public health's interpretation of licensing requirement to exclude psychologists from medical staffs), aff'd, *818 F.2d 1337 (7th Cir. 1987); Clemons v. Fairview Med. Ctr., Inc., 449 So. 2d 788, 789-90 (Ala. 1984)* (holding physical therapist might be member of medical staff entitled to protection under the bylaws); *Lewisburg Cmty. Hosp., Inc. v. Alfredson, 805 S. W.2d 756, 760 (Tenn. 1991)* (noting bylaws define "Medical Staff" as licensed physicians, dentists, and podiatrists); *Ogrodowczyk v. Tennessee Bd. for Licensing Health Care Facilities, 886 S. W.2d 246, 251-52 (Tenn. Ct. App. 1994)* (noting that under Tennessee law medical staff members must be graduates of approved programs of medicine, dentistry, osteopathy, podiatry, psychology, nurse midwifery, or optometry); 12 Va. Admin. Code 5-410-10 (West, WESTLAW through Aug. 14, 2000) (defining terms regarding hospital employees, their activities, and hospital facilities as used in this chapter of the Code). See also *Cooper v. Forsyth County Hosp. Auth., Inc., 789 F.2d 278, 279 (4th Cir. 1986)* (upholding bylaws restricting staff membership to physicians and dentists, thus excluding podiatrists); *Wrable v. Cmty. Mem'l Hosp., 501 A.2d 187, 190 (N.J. Super. Ct. Law Div. 1985)* (upholding denial of staff membership to psychiatric nurse), aft'd, *517 A.2d 470 (N.J. Super. Ct. App. Div. 1986); Md. Code Ann., Health-Gen. H*

19-351 (1996) (prohibiting hospitals from denying staff privileges to podiatrists, qualified dentists, and licensed psychologists on a class-wide basis).

Several jurisdictions either have prohibited chiropractors from staff membership or upheld hospital decisions to deny staff membership for chiropractors. See *Petrocco v. Dover Gen. Hosp. &Med. Ctr., 642 A.2d 1016, 1021-27 (N.J. Super. Ct. App. Div. 1994)* (rejecting chiropractor's claim that hospital's refusal to grant him staff privileges constituted violation of due process, defamation, and conspiratorial conduct); *Cohn v. Wilkes Reg'l Med. Ctr., 437 S.E.2d 889, 891-92 (N. C. Ct. App. 1994)* (finding local statues governing hospitals and health services do not require hospitals to give staff privileges to chiropractors); *Fort Hamilton-Hughes Memorial Hosp. Ctr. v. Southard, 466 N.E.2d 903, 905-06 (Ohio 1984)* (finding that statue which protects doctors from discriminatory granting of staff membership but not chiropractors is not violation of equal protection); *Boos v. Donnell, 421 P.2d 644, 647 (Okla. 1966)* (finding hospital has no duty to grant hospital privileges to chiropractors); *Samuel v. Curry County, 639 P.2d 687, 689 (Or. Ct. App. 1982)* (concluding Oregon law does not require grant of hospital privileges to chiropractors because they are not licensed, practicing physicians); *Ogrodowczyk, 886 S. W.2d at 252* (finding local rules precluded hospitals from granting medical staff privileges to chiropractors). See also Fla. Admin. Code Ann. r. 59A-3.217(4)(h) (West, WESTLAW through July 1, 2000) ("nothing contained in the provisions of this section shall require a licensed facility to grant staff privileges to a chiropractor").

n45. See, e.g., *Johnson v. El Paso Pathology Group, P.A., 868 F. Supp. 852, 860 (W.D. Tex. 1994)* ("Having staff privileges at a hospital is not the same as being employed by a hospital."); *Bryant v. Glen Oaks Med. Ctr., 650 N.E.2d 622, 630 (Ill. App. Ct. 1995)* (stating that grant of staff privileges

does not guarantee concurrent employment); *Sullivan v. Baptist Mem'l Hosp.-Golden Triangle, Inc., 722 So. 2d 675, 679 (Miss. 1998)* (observing that staff appointment and clinical privileges do not establish employment contract); *Albain v. Flower Hosp., 553 N.E.2d 1038, 1043 n.5 (Ohio 1990)* ("Physicians with staff privileges have long been considered independent contractors...."), overruled on other grounds by *Clark v. Southview Hosp. & Family Health Ctr., 628 N.E.2d 46 (Ohio 1994); Lyons v. St. Vincent Health Ctr., 731 A.2d 206, 210 (Pa. Commw. Ct. 1999)* ("In most cases, doctors with staff privileges are not employees of the hospital...."); *Bryant v. HCA Health Servs. Of No. Tenn., Inc., 15 S. W.3d 804, 809-10 (Tenn. 2000)* ("A hospital usually provides a staffed facility in which a non-employee physician may perform a procedure.").

n46. *Engelstad v. Virginia Mun. Hosp., 718 F.2d 262, 267 (8th Cir. 1983);* accord, e.g., *Draghi v. County of Cook, 991 F. Supp. 1055, 1058 (N.D. Ill. 1998)* (finding that doctor's appointment to hospital staff does not create an employment contract), aff'd, *184 F.3d 689 (7th Cir. 1999).*

n47. In determining whether a particular relationship is an employment relationship, courts often have looked to the factors identified in the *Restatement (Second) of Agency 220* (1958). See, e.g., *Cmty. for Creative Non-Violence v. Reid, 490 U.S. 730, 751-52 & nn. 18-30 (1989)* (analyzing whether organization's agreement with artist to produce sculpture is "work made for hire" under Restatement principles); *Cilecek v. Inova Health Sys. Servs., 115 F.3d 256, 262-63 (4th Cir. 1997)* (citing Restatement to support notion that doctor under contract with hospital to provide emergency medical services is independent contractor). See also *Restatement (Second) of Agency 2* (1958) (defining master, servant, and independent contractor).

n48. See, e.g., *Diggs v. Harris Hosp.-Methodist, Inc., 847 F.2d 270, 273 (5th Cir. 1988)* ("The hospital does not direct the manner or means by which [plaintiff physician] renders medical care... Plaintiff physician treated her patients in [defendant hospital] without direct supervision."); *St. Luke's Health Sys. v. State, 884 P.2d 259, 264-65 (Ariz. Ct. App. 1994)* (finding that hospital "did not control the details of [physician's] medical practice"); *Sullivan, 722 So. 2d at 680* ("The Hospital does not control or direct the radiologist or the manner in which he performs his services.").

n49. See, e.g., *Cilecek, 115 F.3d at 261-62* (stating that hospital-imposed regulations relating to professional standards for providing health care did not indicate employment relationship); *Diggs, 847 F.2d at 273* ("While it imposes standards upon those permitted to hold staff privileges, the hospital does not direct the manner or means by which [plaintiff physician] renders medical care.").

n50. See, e.g., *Diggs, 847 F.2d at 273* (noting that physician treated patients without direct supervision); *St. Luke's Health Sys., 884 P.2d at 264* (finding that physician "independently admitted his own patients, diagnosed their conditions, and determined the appropriate manner and means of treatment," and was paid directly by patients or insurers).

n51. See *Alexander v. Rush North Shore Med. Cir., 101 F.3d 487, 493 (7th Cir. 1996)* (finding no employment contract between doctor and hospital because manner in which doctor rendered services was primarily in his own control); *Diggs, 847 F.2d at 272-73* (emphasizing hospital's lack of direct control over doctor's means of providing medical care to patients); *St. Luke's Health Sys., 884 P.2d at 264-65* (finding doctor, not hospital, had right to control details and means of work doctor performed); *State Comm'n on Human Relations v. Suburban Hosp., Inc., 686 A.2d 706, 721 (Md. Ct.*

Spec. App. 1996) (finding hospital does not direct manner of doctor's medical care through grant of staff privileges), vacated on other grounds, *704 A.2d 445 (Md. 1998); Sullivan, 722 So. 2d at 680* (finding that hospital does not direct or control delivery of radiologist's services); *State ex rel. Mississippi Ethics Comm'n v. Aseme, 583 So. 2d 955, 959-60 (Miss. 1991)* (indicating grant of hospital privileges does not normally create employment contract between doctor and hospital). See also *Bender v. Suburban Hosp., Inc., 159 F.3d 186, 191 (4th Cir. 1998)* (noting district court's holding that staff privileges did not make physician employee); *Cilecek, 115 F.3d at 260, 263* (concluding that physician under contract to provide emergency medical services at hospital was independent contractor and not employee). But see *Mallare v. St. Luke's Hosp. of Bethlehem, 699 F. Supp. 1127, 1130 (E.D. Pa. 1988)* (holding that jury could find hospital was prospective employer of physician seeking staff privileges for purposes of Title VII claim).

n52. JCAHO Manual, supra note 1, at MS-2. See also id. MS.1.1.2, at MS-2 ("All medical staff members have delineated clinical privileges that define the scope of patient care services they may provide independently in the hospital.").

n53. See Starr, supra note 8, at 166-67 (noting that hospital boards often expanded available positions for "feeders," doctors who could fill their beds).

n54. Roemer & Friedman, supra note 9, at 34.

n55. See Rosner, supra note 21, at 118 (noting "the authority of lay trustees declined as physicians began to exert greater control over the day-to-day services provided their private patients").

n56. See *Restatement (Second) of Agency* 223 cmt. a (1958) (noting physician at hospital not normally servant of hospital but may be in some circumstances). See also, e.g., *Mitchell v. Frank R. HowardMem'l. Hosp., 853 F.2d 762, 766-67 (9th Cir. 1988)* (concluding radiologist under oral contract to provide all radiology services at hospital, to treat hospital patients, and who was paid by hospital could be employee for purposes of Title VII); *Beverley v. Douglas, 591 F. Supp. 1321, 1327 (S.D.N.Y. 1984)* (distinguishing full-time staff physicians from self-employed physicians with private practices); *Albain v. Flower Hosp., 553 N.E.2d 1038, 1043 n.5 (Ohio 1990)* ("Hospitals often employ full-time salaried physicians"), overruled on other grounds by *Clark v. Southview Hosp. & Family Health Ctr., 628 N.E.2d 46 (Ohio 1994).*

n57. See Ed Egger, If Physician Unionization Trend Catches On, Hospitals Could be Drastically Affected, 17 Health Care Strategic Mgmt. 10, 10-11 (1999) (citing AMA 1996 report that forty percent of physicians are employed by health care organizations (including medical schools, hospitals, government entities, and HMOs)). See also Marsha Gold, The Changing US Health Care System: Challenges for Responsible Public Policy, 77 Milbank Q. 3, 14-15 (1999) (noting shift from self-employment to employment in physician-owned groups and groups owned by others).

n58. See, e.g., *Illinois Psychological Ass'n v. Falk, 638 F. Supp. 876, 877 (N.D. Ill. 1986)* ("Only persons on the medical staff may admit patients, order medical treatment, and vote on hospital policies"), affd, *818 F.2d 1337 (7th Cir. 1987);* Ariz. Admin. Code R9-10-214(B) (West, WESTLAW through Dec. 31, 1999) ("Patients shall be admitted to the hospital by a member of the medical staff in accordance with medical staff bylaws, and shall be under the general care of a physician."); Ill. Admin. Code tit. 77, 250.240(b)(1) (West, WESTLAW through Aug. 25, 2000) (providing all patients

must be admitted by a member of medical staff with admitting privileges); id. 250.330(a) (stating that medication and treatment at hospital require order of medical staff member). See also JCAHO Manual, supra note 1, MS.6.5.1, at MS-12 ("Management of a patient's general medical condition is the responsibility of a qualified physician member of the medical staff.").

n59. See JCAHO Manual, supra note 1, at MS-2 (defining "clinical privileges"); id. MS.1.1.2, at MS-2 ("All medical staff members have delineated clinical privileges that define the scope of patient care services they may provide independently in the hospital."). See also, e.g., Ariz. Admin. Code R9-10-214(D) (West, WESTLAW through Dec. 31, 1999) ("Clinical privileges of each medical staff member shall be delineated in writing.").

n60. JCAHO Manual, supra note 1, at MS-2; id. MS.6.4, at MS-12. See also *Bryant v. Glen Oaks Med. Ctr., 650 N.E.2d 622, 624 (Ill. App. Ct. 1995)* (observing that bylaws defined "clinical privileges" as "the permission granted to a practitioner to render specific diagnostic, therapeutic, psychiatric, medical, dental, podiatric or surgical services").

n61. See *Garibaldi v. Applebaum, 653 N.E.2d 42, 44 (Ill. App. Ct. 1995)* (distinguishing between staff privileges and clinical privileges); *Dutta v. St. Francis Reg'l Med. Cir., Inc., 867 P.2d 1057, 1061 (Kan. 1994)* ("A grant of medical staff membership does not guarantee a companion grant of clinical privileges."); *Bartley v. Eastern Maine Med. Ctr., 617 A.2d 1020, 1022-23 (Me. 1992)* (establishing that staff privileges "signify that a doctor is qualified to practice at the hospital... [but] the right to exercise the privileges, however, is a separate matter."); David J. Behinfar, Exclusive Contracting Between Hospitals and Physicians and the Use of Economic Credentialing, *1 DePaul J. Health Care L 71, 78 (1996)* (describing staff privileges as minimum standards

that may be supplemented by clinical privileges, which serve as a grant of right to perform services at the hospital). "Medical staff privileges" or simply "staff privileges" are sometimes equated with "staff membership." See, e.g., *Garibaldi, 653 N.E.2d at 44* (comparing staff privileges with staff membership); *Lewisburg Crnty. Hosp., Inc. v. Alfredson, 805 S.W.2d 756, 760 (Tenn. 1991)* (describing medical staff privileges as flowing from staff membership). When equated with staff membership, staff privileges are distinct from clinical privileges. Cf. JCAHO Manual, supra note 1, at MS-2 (defining "clinical privileges"). But see *42 U.S.C. 11151(3)* (1995) (defining "clinical privileges" to include membership on medical staff); *Engelstad v. Virginia Mun. Hosp., 718 F.2d 262, 266-67 (8th Cir. 1983)* (equating "clinical privileges" with "staff privileges"); *Clemons v. Fairview Med. Ctr., Inc., 449 So. 2d 788, 789 (Ala. 1984)* ("The terms "medical staff privileges' and "clinical privileges' refer simply to the right of an individual to treat patients at [the hospital]").

n62. See *Pepple v. Parkview Mem'l Hosp., Inc., 536 N.E.2d 274, 275 (Ind. 1989)* (allowing hospital to limit doctor's surgical privileges).

n63. See JCAHO Manual, supra note 1, MS.6, at MS-11.

n64. Id. at MS-11. Some professional personnel may have clinical privileges but are not members of the medical staff. See Kan. Admin. Regs. 28-34-6a(e)(5) (West, WESTLAW through Feb. 14, 1999) (requiring that hospital bylaws delineate "clinical privileges and duties of professional personnel" who work in "clinical capacity" but "who are not members of the medical staff").

n65. See JCAHO Manual, supra note 1, MS.2, MS.2.1, at MS-3 (establishing that bylaws are adopted by the medical staff).

n66. Id. MS.2.3 to MS.2.3.8, at MS-3 - MS-4.

n67. See *42 C.F.R. 482.22(c)(2) (1999)* (requiring identification of staff membership categories for hospitals participating in Medicare and Medicaid); JCAHO Manual, supra note 1, MS.2.3.4, at MS-3 (requiring description of staff's organization).

n68. William P. Isele, The Hospital Medical Staff: Its Legal Rights and Responsibilities 29 (1984). See also *Davila-Lopes v. Zapata, 111 F.3d 192, 194 (1st Cir. 1997)* (bylaws provided for active, associate, special associate, courtesy, and consulting categories of staff); *Jackaway v. Northern Dutchess Hosp., 526 N. Y.S.2d 599, 599-600 (N. Y. App. Div. 1988)* (contrasting rights and privileges of active staff with courtesy staff).

n69. Fla. Admin. Code Ann. r. 59A-3.220(1) (West, WESTLAW through July 1, 2000). See also, e.g., Ariz. Admin. Code R9-10-214(A) (West, WESTLAW through Dec. 31, 1999) (requiring that hospitals have organized medical staff that answers to governing body for the quality of health care rendered to patients and for ethical conduct of its members); JCAHO Manual, supra note 1, MS. 1, at MS-2 (staff has "overall responsibility for the quality of the professional services provided by individuals with clinical privileges").

n70. See JCAHO Manual, supra note 1, MS.5.1, at MS-7 (establishing that appointments and reappointments made by governing board are based on medical staff recommendations); id. MS.5.3. I, at MS-7 (establishing that mechanisms for appointment and grant of privileges are "approved and implemented by the medical staff and governing body"); id. MS.5.4.1, at MS-8 ("Each clinical department makes recommendations to the medical staff regarding professional criteria for clinical privileges.").

n71. JCAHO Manual, supra note 1, at MS-7.

n72. See, e.g., Kan. Admin. Regs. 28-34-6a(b) (West, WESTLAW through Jan. 1, 1999) ("The medical staff shall adopt bylaws which define the requirements for admission to staff membership and for the delineation and retention of clinical and admitting privileges."); JCAHO Manual, supra note 1, at MS-7 ("The medical staff is responsible for a credentialing process.").

n73. JCAHO Manual, supra note 1, MS.5.3, MS.5.3.1, at MS-7. See also, e.g., I11. Admin. Code tit. 77, 250.310(a)(1) (West, WESTLAW through Aug. 25, 2000) (stating that medical staff must establish written procedure for consideration of applications for staff membership and clinical privileges).

n74. See JCAHO Manual, supra note 1, MS.5.4.1, at MS-8 (requiring recommendations from departments).

n75. See, e.g., Ariz. Admin. Code R9-10-214(D) (West, WESTLAW through Dec. 31, 1999) (stating that medical staff shall recommend to governing body "physicians and other licensed practitioners considered eligible for new and continued membership on the medical staff'); Fla. Admin. Code Ann. r. 59A-3.220(2)(d) (West, WESTLAW through July 1, 2000) (requiring medical staffs to "review" all applications by licensed practitioners for new and continued membership on medical staff and to endorse qualified applicants to the governing authority); Kan. Admin. Regs. 28-34-6a(d) (West, WESTLAW through Jan. 1, 1999) (declaring governing body shall decide upon "each recommendation for appointment to the medical staff" and that application process is to be considered in accordance with medical staffs bylaws); JCAHO Manual, supra note 1, MS.5.1, at MS-7 (establishing that governing body makes appointments based on medical staff recommendations).

n76. See, e.g., *Colo. Rev. Stat. Ann. 25-3-103.5(1)* (1999) (listing factors hospital may consider); *Fla. Stat. Ann. 395.0191(4)* (West Supp. 2000) (listing factors hospital may consider). The hospital has discretion to determine the specific information required. See JCAHO Manual, supra note 1, at MS-7 (allowing individual organization to determine information required for decision making).

n77. See *Tex. Health & Safety Code Ann. 241.101 (c)* (West Supp. 2000) (requiring procedural due process for staff membership review).

n78. See *D.C. Code Ann. 32-1307 (a), (f)* (1998) (requiring "reasonable nondiscriminatory standards"); *Neb. Rev. Stat. Ann. 71-2048.01* (Michie 1999) (requiring establishment of "reasonable standards and procedures" in application process).

n79. See *D.C. Code Ann. 32-1307 09* (1998); *Ga. Code Ann. 31-7-7* (Michie 1996) (setting forth application process requirements for government-owned hospitals); *Va. Code Ann. 32.1-134.1* (Michie 1997) (requiring application review within sixty days).

n80. See, e.g., *Va. Code Ann. 32.1-134.1* (Michie 1997) (providing that reasons for denial must be in writing and provided to physician).

n81. See, e.g., *Adkins v. Sarah Bush Lincoln Health Ctr., 544 N.E.2d 733, 736 (Ill. 1989)* (involving annual appointments); *Ray v. St. John's Health Care Corp., 582 N.E.2d 464, 467 (Ind. Ct. App. 1991)* (involving two year appointments); *Ritter v. Bd. of Comm'rs, 637 P.2d 940, 944 (Wash. 1981)* (involving annual appointments); *Md. Code Ann., Health-Gen. II 19-319(e)(2)(iii)* (Supp. 1999) (requiring reappointment process at least every two years); JCAHO Manual, supra note 1, MS.5.11 at MS- 10 ("Appointment or

reappointment to the medical staff and the granting, renewal. or revision or clinical privileges are made for a period of no more than two years.").

n82. *Md. Code Ann., Health-Gen. H 19-319(e)(2)(iii)* (Supp. 1999).

n83. See JCAHO Manual, supra note 1, MS.5.12 to MS.5.12.3, at MS-10 ("Appraisal for reappointment to the medical staff or renewal or revision of clinical privileges is based on ongoing monitoring of information concerning the individual's professional performance; judgment; and clinical or technical skills.").

n84. See, e.g., *Fla. Stat. Ann. 395.0193(2),* (3) (West, WESTLAW through Dec. 31, 1999) (describing peer review procedures); Kan. Admin. Regs. 28-34-6a(e)(10) (West, WESTLAW through Jan. 1, 1999) (requiring medical staff bylaws establish procedures to monitor "the performance of the medical staff and each department or service" and make recommendations to the medical staff and multidisciplinary committee); Kan. Admin. Regs. 28-34-6a(e)(11) (mandating peer review must also encompass medical staff member's performance in regard to "relevant ethics and statutory codes of conduct); JCAHO Manual, supra note 1, MS.8 to MS.8.4, at MS-49.

n85. See JCAHO Manual, supra note 1, at MS-49 (stating that "members of the medical staff are involved in activities to measure, assess, and improve performance on an organizationwide basis" including "measurement of outcomes and of processes."); 1 Tom Curtis, The Medical Staff, Treatise on Health Care Law 6.0411] (Michael G. MacDonald et al., eds. 1999).

n86. See, e.g., *Fla. Stat. Ann. 395.0193(3)* (West 1999) (describing discipline procedure); *Miss. Code Ann. 73-25-93(1)* (1999) (authorizing hospital to suspend, deny, revoke or limit privileges if warranted).

n87. JCAHO Manual, supra note 1, MS.2.3.3, at MS-3.

n88. See, e.g., *Cal. Bus. & Prof. Code 809.5(a)* (West 1990 & Supp. 2000) (citing grounds for immediate suspension); *Fla. Star. Ann. 395.0193(3)* (West 1999) (listing grounds for disciplinary measures); 59 Fla. Admin. Code Ann. r. 59A-3.217(5) (West WESTLAW through July 1, 2000) (stating that governing body has power to decline any staff member for "good cause" which includes but is not limited to "incompetence, negligence," substance abuse, "mental or physical impairment" that may negatively affect patient care, and "behavior disruptive to hospital environment"); *210 Ill. Comp. Stat. Ann. 85/10.4 (b)(2)(C)(i)* (West Supp. 2000) (allowing suspension without hearing if staff member presents "immediate danger" to others).

n89. Cf. Sheree Lynn McCall, A Hospital's Liability for Denying, Suspending and Granting Staff Privileges, *32 Baylor L Rev. 175, 175 (1980)* ("A physician's livelihood is dependent on acquiring and maintaining hospital staff privileges. This access to hospital facilities is necessary for most physicians to adequately treat and care for patients, to maintain their medical practice, and to pursue their medical career.").

n90. See *Silver v. Castle Mem'l Hosp., 497 P.2d 564, 571 (Haw. 1972)* ("The doctor has an interest in being able to pursue his profession which requires that the necessary facilities be available to him."); *Burkhart v. Cmty. Med. Ctr., 432 S.W.2d 433, 436 (Ky. 1968)* (discussing the rights of physicians to staff membership in hospital); 1 Barry R. Furrow, et al., Health Law 7-1 at 449 (1995) (stating access to

hospitals is essential for a doctor to be successful practicing medicine); Note, The Physician's Right to Hospital Staff Membership: The Public-Private Dichotomy, *1966 Wash. U. L.Q. 485, 510-11* (noting for doctor to be successful, he/she must have access to hospitals).

n91. See *Holmes v. Hoemako Hosp., 573 P.2d 477, 480 (Ariz. 1977)* (Struckmeyer, V.C.J., dissenting) (noting doctor was the only doctor in community and hospital was the only hospital serving that community); *Lawler v. Eugene Wuesthoff Mem'l Hosp., 497 So. 2d 1261, 1264 (Fla. Dist. Ct. App. 1986)* (stating loss of privileges "is a serious disadvantage to his or her ability to continue to practice in the community); *Greisman v. Newcomb Hosp., 192 A.2d 817, 821 (N.J. 1963)* (observing that only hospital in metropolitan area had virtual monopoly); *Kelly v. St. Vincent Hosp., 692 P.2d 1350, 1353 (N.M. Ct. App. 1984)* (noting that because many towns are isolated with only one hospital, a staffing decision can essentially deny a doctor opportunity to practice medicine); *Ritter v. Bd. of Comm'rs of Adams County Pub. Hosp. Dist. No. 1, 637 P.2d 940, 949 (Wash. 1981)* (Dore, J., dissenting) (noting physician's predicament in one-hospital town).

n92. See JCAHO Manual, supra note 1, MS.5.5, at MS-8; Chester A. Groseclose, Jr., Hospital Privilege Cases: Braving the Dismal Swamp, *26 S.D.L. Rev. 1, 1 (1981)* (noting that hospital staff bylaws require such disclosures). For examples of bylaws requiring such disclosures see Joint Commission on Accreditation of Hospitals, Guidelines for the Formulation of Medical Staff Bylaws 1971 at 10 (1977) [hereinafter "JCAH Guidelines for Bylaws"]. See also, e.g., Bylaws of the Yale-New Haven Hosp., Inc. for the Medical Staff art. V, B(3) (Sept. 8, 1999) <http://www.ynhh.com/med<uscore>prof/bylaws/contents.html> [hereinafter "Yale-New Haven Hosp. Bylaws"]; Presbyterian Hosp. Medical Staff By-Laws 1995 art. III, 4(1)

(revised Jan. 18, 1995) <http://cpmcnet.columbia.edu/dept/assurance/phby0000.html> [hereinafter "Presbyterian Hosp. Bylaws"]; The Hospital Council of Western Pennsylvania, Model Medical Staff Bylaws 4.2-2 (visited October 21, 2000) <http://www.hcwp.org/meddirfm/bylaws.htm> [hereinafter "HCWP Model Bylaws"]; The University of Texas Medical Branch, Bylaws and Rules and Regulations of the Medical Staff: The University of Texas Medical Branch at Galveston 2.3.5, 2.3.6.6 Art. IV (rev. Feb. 17, 1999) <http://www.utmb.edu/policy/bylaws>[hereinafter TMB Bylaws"].

n93. See Barbara A. Blackmond, Current Issues - The National Practitioner Data Bank and Hospital Peer Review, *7 Health Law. 1, 6 (1993).*

n94. See *Mateo-Woodburn v. Fresno Cmty. Hosp., 270 Cal. Rptr. 894, 903 (Cal. Ct. App. 1990)* (stating adverse action based on professional inadequacy or misconduct severely impairs ability to become staff member at another hospital); *State ex rel Bronaugh v. City of Parkersburg, 136 S.E.2d 783, 788 (W. Va. 1964)* (observing that public hospital's denial of privileges without a hearing was based on denial of privileges at another hospital).

n95. JCAHO Manual, supra note 1, MS.5.4.3.2, at MS-8.

n96. See *45 C.F.R. 60.1* (1999) (noting establishment of data bank on physician, dentist and healthcare providers for competency and conduct).

n97. See Ruth E. Flynn, Demand for Public Access to the National Practitioner Data Bank: Consumers Sound Their Own Death Cry, *18 Hamline J. Pub. h & Pol'y 251, 251 (1996)* (stating Data Bank established by the Act became operational on Sept. 1, 1990).

n98. See *42 U.S.C. 11101,* et seq. (1995) (addressing national problem of medical malpractice and need to restrict ability of physicians to travel from state to state); *Imperial v. Suburban Hosp. Ass'n Inc., 37 F.3d 1026, 1028 (4th Cir. 1994)* (discussing HCQIA). See also H.R. Rep. No. 903, 99th Cong.2d Sess. (1986), reprinted in 1986 U.S.C.C.A.N. 6384-6391 (detailing purpose of professional review committees, including collection and dissemination of malpractice information and adverse actions against medical providers).

n99. See *42 U.S.C. 11111,* 11151(11) (1995) (defining professional review body and limiting damages for professional review actions). See also, e.g., *Brader v. Allegheny Gen. Hosp., 167 F.3d 832, 834 (3d Cir. 1999)* (finding hospital met safe harbor requirement under HCQIA); *Wayne v. Genesis Med. Ctr., 140 F.3d 1145, 1148 (8th Cir. 1998)* (articulating HCQIA protects hospitals from liability when specific review actions followed). Underreporting to the Data Bank may be undermining its effectiveness however. Those concerned that hospitals are underreporting physician disciplinary actions to the Data Bank cite a U.S. Department of Health and Human Services report that from September 1990 to September 1998, about sixty-seven percent of all United States Hospitals had not reported a single disciplinary action against a doctor. Letter of Rep. Tom Bliley, Chairman of the House Committee on Commerce, to Richard Davidson, President, American Hospital Association, Nov. 23, 1999 (visited Oct. 21, 2000) http://www.house.gov/commerce> (quoting report and sixty-seven percent statistic). According to Thomas Croft, Director of the Division of Quality Assurance, Health

Resources and Services Administration, the Department of Health and Human Services is considering a proposal to seek a legislative change allowing imposition of monetary penalties where hospitals fail to report reportable actions. Assessing the Operation of the National Practitioner Data Bank: Oversight Hearing Before the Subcommittee on Oversight & Investigations of the House Comm. on Commerce, 106th Congress. (Mar. 16, 2000) (statement of Thomas Croft, Director of the Division of Quality Assurance, Health Resources and Services Administration) (visited Oct. 21, 2000) <http://www.house.gov /commerce>.

nl00. 42 *U.S.C. ll133(a)(1)(A)(1995); 45 C.F.R. 60.9(a)(1)(i)(1999).* See also *Babcock v. St. Francis Med. Ctr., 543 N.W.2d 749, 755-56 (Neb. Ct. App. 1996)* (citing HCQIA and regulations). The Act also requires the hospital to report when it accepts the surrender of a physician's clinical privileges under certain circumstances. *42 U.S.C. 11133(a)(1)(B)* (1995).

N101.42 *U.S.C. 11151(1)* (1995).

n102. See *42 U.S.C. ll133(b),* 11134(a) (1995); *45 C.F.R. 60.4,* 60.5(c), 60.9(b) (1999) (requiring reporting by board of medical examiners).

n 103. See *42 U.S.C. 11131,* 11132 (1995) (discussing requirement of reports on medical malpractice payments).

n104. See *42 U.S.C. 11137(b)* (1995) (addressing confidentiality of information); *45 C.F.R. 60.11,* 60.13 (1999) (addressing confidentiality of information requested from National Practitioner Data Bank). Congressman Thomas Bliley, Chairman of the House Committee on Commerce, and others have recently advocated opening the National Practitioner Data Bank to the public. See Sandra G.

Boodman, The Right to Know: Still Trying to Open the Database on Doctors, Wash. Post, Mar. 7, 2000, at Z13 (discussing efforts of Senator Ron Wyden and Rep. Bliley to open the Data Bank to the public). On March 1, 2000 and March 16, 2000, Congress held hearings considering the advisability of allowing public access to the National Practitioner Data Bank. The text of several of the statements before House Subcommittee on Oversight and Investigations at those hearings can be found at <http://www.house.gov/commerce> (visited Oct. 21, 2000).Error! Bookmark not defined.

n105. See *42 U.S.C. 11135(a)* (1995), *45 C.F.R. 60.10(a)* (1998) (setting forth the duty of hospitals to obtain information).

n106. See, e.g., *Ca. Code Ann. 31-7-8(a)* (1996) (requiring hospital administrator to submit written report to licensing board concerning denial, restriction or revocation of staff privileges); *Mass. Gen. Laws Ann. ch. 111, 53B* (West Supp. 2000) (requiring report of disciplinary hearing filed with board of registration of medicine within thirty days); *Utah Code Ann. 58-13-5(3)* (1998) (requiring report of adverse action filed with Utah Medical Association within sixty days of event); *University of S. Cal. v. Superior Court, 53 Cal. Rptr. 2d 260, 264 n.6 (Cal. Ct. App. 1996)* (requiring report of denial of staff privileges to Medical Board).

n107. See *Ga. Code Ann. 31-7-809 (1996)* (stating non-compliance may result in loss of permit to operate); *Mass. Gen. Laws Ann. ch. 111, 53B* (West Supp. 2000) (stating non-compliance may result in fine not in excess of $10,000).

n108. One court concluded that "finding gainful employment in the hospital setting after a poor review is unlikely as a result of the provisions of the Health Care

Quality Improvement Act of 1986, *42 U.S.C. 11101-52* (1986), which requires that doctors who have been denied privileges be reported to a national service." *Cooper v. Delaware Valley Med. Ctr., 654 A.2d 547, 551 (Pa. 1995).* See also *Janes v. Centegra Health Sys., 721 N.E.2d 702, 707-08 (Ill. Ct. App. 1999)* (noting pathologist's argument that report of a ""for cause' revocation of his clinical privileges to the National Practitioner Data Bank" would "directly injure his ability to gain future employment as a pathologist anywhere in the country"); Jacqueline Oliverio, Note, Hospital Liability for Defamation of Character During the Peer Review Process: Sticks and Stones May Break My Bones, but Words May Cost Me My Job, *92 W. Va. L. Rev. 739, 740 (1990)* (noting that denial of privileges based on poor performance can have devastating effects on a physician's career).

n109. *Ritter v. Bd. of Comm'rs, 637 P.2d 940, 942 (Wash. 1981).*

n110. *Id. at 942-43.*

n 111. *Id. at 952-53* (Dore, J., dissenting).

n112. Based on this interest, California courts have recognized ""[a] physician's right to pursue his livelihood free from arbitrary exclusionary practices.'" *Webman v. Little Co. of Mary Hosp., 46 Cal. Rptr. 2d 90, 95 (Cal. Ct. App. 1995)* (alteration in original) (citing *Rhee v. E! Camino Hosp. Dist., 247 Cal. Rptr. 244 (Cal. Ct. App. 1988)).*

n113. See *Rao v. Bd. of County Comm'rs, 497 P.2d 591, 592-93 (Wash. 1972)* (discussing applicant's requirement of providing references is in interest of providing quality care and noting hospital's "economic success depends in large degree upon its good reputation").

n114. See infra notes 542-48 and accompanying text for a discussion of the deference courts afford credentialing decisions.

n115. Charitable immunity was first adopted in the United States in *McDonald v. Massachusetts General Hospital, 120 Mass. 432 (1876),* which relied on earlier English cases of dubious authority. See *Bing v. Thunig, 143 N.E.2d 3, 5 (N. Y. 1957)* (citing McDonald for doctrine of charitable immunity); *Pierce v. Yakima Valley Mem'l Hosp. Ass'n, 260 P.2d 765, 768 (Wash. 1953)* (stating that McDonald court relied on English authority as sole basis for its holding). Other American courts followed McDonald's lead. See, e.g., *Perry v. House of Refuge, 63 Md. 20, 26-28 (Md. 1885)* (discussing charitable immunity); *Richardson v. Carbon Hill Coal Co., 32 P. 1012, 1013 (Wash. 1893)* (same); *Downs v. Harper Hosp., 60 N. W. 42, 43 (Mich. 1894)* (same); *Lindler v. Columbia Hosp., 81 S.E. 512, 512 (S.C. 1914)* (same); *Schloendorff v. Society of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914)(same).*

n116. See 1 Barry R. Furrow, et al., Health Law 7-1, at 449-51 (1995) (discussing governmental immunity).

n117. See, e.g., *President of Georgetown College v. Hughes, 130 F.2d 810, 827 (D.C. Cir. 1942)* (rejecting charitable immunity doctrine); *Silva v. Providence Hosp., 97 P.2d 798, 802 (Cal. 1939)* (declining to follow charitable immunity doctrine); *Parker v. Port Huron Hosp., 105 N. W.2d 1, 14-15 (Mich. 1960)* (adopting new rule of no charitable immunity for hospitals); *Bing, 143 N.E.2d at 8-9* (finding nonliability "out of tune" with modern life); *Pierce, 260 P.2d at 774* (abrogating nonliability doctrine). Even before abrogating the doctrine, courts had begun to impose numerous exceptions to charitable immunity, prompting one court to observe, "in this state, as elsewhere, the immunity rule has been "devoured' with exceptions." *Pierce, 260 P.2d at 772.* See generally John D. Hodson, Annotation, Liability of Hospital or Sanitarium for Negligence of

Physician or Surgeon, *51 A.L.R. 4th 235 (1987)* for a discussion of cases holding hospitals liable for acts of their agents.

n118. See, e.g., *Pierce, 260 P.2d at 768* (noting "the "rule' is that one is liable for his negligent or tortious conduct. The "rule' is that charity is no defense to tort. The immunity from suit granted charitable institutions, in actions involving tortious conduct, is an exception to these rules.") (citations omitted).

n119. Cf., e.g., *Vargo v. Sauer, 576 N. W.2d 656, 660, 664 (Mich. 1998)* (noting "governmental agencies are statutorily immune from tort liability "except as otherwise provided'" and defining governmental agency as "the state, political subdivisions, and municipal corporations") (alteration in original); *Salcedo v. El Paso Hosp. Dist., 659 S. W.2d 30, 31 (Tex. 1983)* (noting "the E1 Paso Hospital District is a political subdivision of the State of Texas. As such, it is not liable for damages unless the negligent or wrongful act alleged falls within the statutory waiver of immunity.").

n120. See *Salcedo, 659 S. W.2d at 30* (finding statutory waiver applicable); *Condemarin v. University Hosp., 775 P.2d 348, 364 (Utah 1989)* (finding portions of governmental immunity act unconstitutional). See Furrow, supra note 116, at 7-1, at 450-51 (discussing governmental immunity).

n121. See infra notes 125-47 and accompanying text for a discussion of the various contexts in which courts have held hospitals liable for medical staff members' malpractice.

n122. See Daniel L. Icenogle, Annotation, Hospital Liability as to Diagnosis and Care of Patients in Emergency Room, *58 A.L R.5th 613 (1998)* (discussing hospital liability).

n123. See, e.g., *Gilbert v. Sycamore Mun. Hosp., 622 N.E.2d 788, 794-96 (Ill. 1993)* (discussing agency principles); *Paintsville Hosp. Co. v. Rose, 683 S. W.2d 255, 256-58 (Ky. 1985)* (discussing ostensible agency); *Clark v. Southview Hasp. & Family Health Ctr., 628 N.E.2d 46, 53 (Ohio 1994)* (utilizing doctrine of agency by estoppel to find hospital liable); *Themins v. Emanuel Lutheran Charity Bd., 637 P.2d 155, 159 (Or. Ct. App. 1981)* (applying ostensible agency doctrine); *Rodrigues v. Miriam Hosp., 623 A.2d 456, 462 (R.I. 1993)* (applying, for the first time, doctrine of apparent authority); *Baptist Mem'l Hosp. Sys. v. Sampson, 969 S. W.2d 945, 947-48 (Tex. 1998)* (applying doctrine of ostensible agency). See also Martin C. McWilliams, Jr. & Hamilton E. Russell, III, Hospital Liability for Torts of Independent Contractor Physicians, *47 S.C. L Rev. 431, 445-52 (1996)* (discussing agency principles); *Restatement (Second) of Agency 267* (1958) (finding reliance upon care or skill of servant creates agency); *Restatement (Second) of Torts 429* (1965) (outlining aspects of agency relationship).

n124. See *Jackson v. Power, 743 P.2d 1376, 1384-85 (Alaska 1987)* (discussing "non-delegable duty" theory); *Simmons v. Tuomey Reg'l Med. Ctr., 533 S.E.2d 312, 320-21 (S.C. 2000)* (imposing a nondelegable duty on hospitals). See also *Martell v. St. Charles Hosp., 523 N.Y.S.2d 342, 352 (N.Y. Sup. Ct. 1987)* (not citing nondelegable duty, but reaching same result on public policy grounds). But see *Baptist Mem'l Hosp. Sys. v. Sampson, 969 S.W.2d 945, 947-49 (Tex. 1998)* (reversing court of appeals' holding imposing nondelegable duty).

n125. *743 P.2d 1376 (Alaska 1987).*

n126. *Id. at 1381-82.*

n127. *Id. at 1385.*

n128. McWilliams & Russell, supra note 123, at 457 (quoting *Albian v. Flower Hosp., 553 N.E.2d 1038, 1046 (Ohio 1990)*). See also *Clark v. Southview Hosp. & Family Health Ctr., 628 N.E.2d 46, 54 (Ohio 1994)* (Moyer, C.J., dissenting) (accusing majority of making "a hospital the virtual insurer of its independent physicians"); *id. at 56* (Wright, J.J., dissenting) (claiming that "from this day on no malpractice action evolving out of an incident within a hospital will be brought without joining the medical facility as a co-defendant").

n129. See *Doctors Hosp. v. Bonner, 392 S.E.2d 897, 906-07 (Ga. Ct. App. 1990)* (holding hospital can be liable under apparent authority doctrine); *Kashishian v. Port, 481 N. W.2d 277, 284-86 (Wis. 1992)* (same); *Sharsmith v. Hill, 764 P.2d 667, 672-73 (Wyo. 1988)* (same). See also Kenneth S. Abraham & Paul C. Weiler, Enterprise Medical Liability and the Evolution of the American Health Care System, *108 Harv. L. Rev. 381, 388 (1994)* (finding apparent authority creates liability for hospital even if staff contracted to provide services and are not employees).

n130. *211 N.E.2d 253 (IlL 1965).*

n131. *Darling, 211 N.E.2d at 255.*

n132. *Id. at 255-56.*

n133. *Id. at 256.*

n134. *Id.*

n135. *Id.*

n136. *Darling, 211 N.E.2d at 257* (quoting *Bing v. Thunig, 143 N.E.2d 3, 8 (N. Y. 1957)*). One commentary accurately notes that while Darling is widely credited with taking the first step toward adopting corporate liability, its

principal focus was actually the malpractice of the hospital nursing staff rather than the hospital's responsibility for the malpractice of the attending physician. See Abraham & Weiler, supra note 129, at 390 n.34 (noting that principle focus of Darling was negligence of hospital staff in failing to monitor and report on deteriorating condition of surgical patient).

n137. See, e.g., *Fridena v. Evans, 622 P.2d 463, 466 (Ariz. 1980)* (adopting corporate negligence theory); *Insinga v. LaBella, 543 So. 2d 209, 213-14 (Fla. 1989)* (citing Darling and adopting corporate negligence doctrine); *Corleto v. Shore Mem'l Hosp., 350 A.2d 534, 539 (N.J. Sup. Ct. Law Div. 1975)* (finding vicarious liability where hospital contracted with incompetent physician); *Diaz v. Feil, 881 P.2d 745, 749 (N.M. Ct. App. 1994)* (clarifying corporate negligence doctrine adopted in New Mexico); *Bost v. Riley, 262 S.E.2d 391, 396 (N.C. Ct. App. 1980)* (citing Darling for hospital's duty to patient); *Strubhart v. Perry Mem'l Hosp. Trust Auth., 903 P.2d 263, 275-76 n. 13 (Okla. 1995)* (reviewing jurisdictions adopting corporate negligence doctrine); *Thompson v. Nason Hosp., 591 A.2d 703, 707 (Pa. 1991)* (finding hospital liable under corporate negligence doctrine); *Rodrigues v. Miriam Hosp,, 623 A.2d 456, 462-63 (R.I. 1993)* (applying doctrine of corporate negligence where hospital failed to exercise reasonable care selecting staff); *Denton Reg'l Med. Ctr. v. LaCroix, 947 S.W.2d 941, 950 (Tex. Ct. App. 1997)* (declaring, under Texas law, hospital may be independently liable for injury); *Pedroza v. Bryant, 677 P.2d 166, 169-70 (Wash. 1984)* (detailing history of corporate negligence theory and adopting corporate negligence). But see *Gafner v. Down East Cmty. Hosp., 735 A.2d 969, 974 (Me. 1999)* (refusing to adopt corporate liability theory as formulated in Darling and Thompson); McWilliams & Russell, supra note 123, at 473-74 (criticizing theory as attempt to make hospital insurer for all medical staff).

n138.591 *A.2d 703 (Pa. 1991).*

n139. *Thompson, 591 A.2d at 707-08* (citations omitted).

n140. See *Insinga, 543 So. 2d at 213-14* (finding duty to "select and retain" competent staff); *Strubhart, 903 P.2d at 276-78* (discussing selection and retention of hospital staff); *Rodrigues, 623 A.2d at 462-63* (discussing selection and review of staff privileges).

n141. See, e.g., *Insinga, 543 So. 2d at 214* (imposing duty on hospital to select and retain competent physicians: "The hospital will only be responsible for the negligence of an independent physician when it has failed to exercise due care in the selection and retention of that physician on its staff').

n142. See, e.g., *Humana Med. Corp. v. Traffanstedt, 597 So. 2d 667, 669 (Ala. 1992)* (requiring implicitly some proof staff member was negligent); *Johnson v. Misericordia Cmty. Hosp., 301 N. W.2d 156, 163-64 (Wis. 1981)* (discussing concepts of negligence and duty).

n143. *Thompson, 591 A.2d at 709* (Flaherty, J., dissenting).

n144. *Abraham & Paul C. Weiler, supra* note 129, at 393.

n145. Id.

n146. *Hongsathavij v. Queen of Angels/Hollywood Presbyterian Med. Ctr., 73 Cal. Rptr. 2d 695, 707 (Cal. Ct. App. 1998)* (citations omitted).

n147. *Holmes v. Hoemako Hosp., 573 P.2d 477, 479 (Ariz. 1977).* President Clinton's proposal that hospitals be required to report medical errors that result in death or serious harm has heightened concerns of increased legal liability for hospitals. See Julie Marquis & Alissa J. Rubin, National Perspective Health Hospitals, Doctors Fear Fallout for Call for Error Reporting, L.A. Times, Feb. 23, 2000, at A-5. ("Hospital and physician organizations voiced strong concerns... about President Clinton's proposal for mandatory reporting of serious or deadly medical errors, saying it could lead to a proliferation of malpractice lawsuits and encourage a "culture of blame' in medicine."). See also Report of the Quality Interagency Coordination Task Fource (QulC) to the President, Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact (Feb. 2000) (recommending a mandatory reporting system by hospitals of certain medical errors) (visited Oct. 21, 2000) <www.quic.gov>.

n148. American Med. Ass'n, Policy Compendium 230.975 at 197 (1993); accord *210 Ill. Comp. Stat. Ann. 85/3(b)(3)* (West 1993) (codifying AMA definition). See also John D. Blum, Economic Credentialing: A New Twist in Hospital Appraisal Processes, *12 J. Legal Med. 427, 428-29 (1991)* (discussing meaning of "economic credentialing").

n149. See Blum, supra note 148, at 443 (discussing economic credibility); Behinfar, supra note 61, at 71, 83-84 (same); Daniel D. King & Joel T. Allison, Medical Staff Credentialing: Taking Steps to Avoid Liability, Def. Couns. J. 107, 1112-13 (Jan. 1994) (finding exclusive contracts entered into to improve hospitals' economic situations). Of course the decision to enter an exclusive contract may result from any number of factors, many of which may be legitimate quality of care concerns. Hospitals with primarily economic motives, recognizing the potential perils of economic credentialing, may choose to identify plausible

non-economic justifications for their decisions to avoid criticism or litigation.

n150. See Brad Dallet, Note, Economic Credentialing: Your Money or Your Life!, *4 Health Matrix 325, 342 & nn.98-101 (1994)* (discussing economic credentialing). See Judith E. Orie, Comment, Economic Credentialing: Bottom-Line Medical Care, *36 Duq. L Rev. 437, 441-42 (1998)* for a discussion of criteria often used in economic credentialing.

n151. See American Med. Ass'n, Policy Compendium 230.975, 230.976 at 197 (1993) ("The AMA... strongly opposes the practice of economic credentialing...."); Orie, supra note 150, at 442 ("The AMA and other medical organizations are vehemently opposed to economic credentialirtg."). The AMA's vigorous opposition continues apace. In a December 11, 1999 letter, AMA Executive Vice President E. Ratcliffe Anderson "asked the Inspector General's Office of the Department of Health and Human Services to declare hospital "exclusive credentialing' arrangements a violation of federal fraud laws." Thorn Wilder, AMA Calls "Exclusive Credentialing' By Hospitals a Fraud Violation, 9 BNA's Health Law Reporter 344 (Mar. 9, 2000). In the letter, Anderson stated that "economic credentialing is a troubling phenomenon." Id.

n152. See Richard A. Feidstein, Economic Credentialling and Exclusive Contracts, *9 Health Law 1, 1 (1996)* (stating that hospitals "face increasing pressure to cut costs and increase efficiencies," and therefore "increasingly make credentialing decisions on economic grounds"); Orie, supra, note 150, at 438 ("The terms "cost efficiency' and "cost containment,' frequently touted by hospitals, are merely euphemisms for economic credentialing... As hospitals consolidate, they are forced to focus even more on financial considerations, rather than patient outcome."); id. at 448 ("Increasingly, hospitals are looking to economic

credentialing to mitigate the financial pressures imposed by governmental and insurance company payors."); Howard Larkin & Brian McCormick, The Many Faces of Economic Credentialing, 35 Am. Med. News 3 (July 20, 1992).

n153. See Brian A. Dahl, Economic Credentialing: The Propriety of Managing Physician Costs Through Privileging, 44 J. Healthcare Mgmt. 302, 302 (1999) (economic credentialing "is becoming increasingly prevalent"); Larkin & McCormick, supra note 152, at 3 ("It's unclear how widespread economic credentialing is, but many signs point to increasing prevalence.")

n154. See *Ind. Code Ann. 16-21-2-5(3)(C)* (West Supp. 2000) (recognizing "efficient and effective use of hospital resources" as criteria for staff privileges); *Ind. Code Ann. 16-22-3-9(c)(3)* (West 1997) (allowing standards identifying "efficient and effective utilization of hospital resources"); cf. *Williams v. Hobbs, 460 N.E.2d 287, 292 (Ohio Ct. App. 1983)* (approving termination of radiology privileges in compliance with exclusive contrac0; *Lyons v. St. Vincent Health Ctr., 731 A.2d 206, 212 (Pa. Commw. Ct. 1999)* (upholding refusal to renew radiologist's clinical privileges due to exclusive contract with radiology group).

n155. *Ind. Code Ann. 16-21-2-5(3)(C),* 16-22-3-9(c)(3)(West Supp. 2000).

n156. *210 Ill. Comp. Star. Ann. 85/2(b)* (West Supp. 2000). See also *210 Ill. Comp. Stat. Ann. 85/10.4(b)(1)(E),* (b)(2)(B), (b)(3) (West Supp. 2000) (requiring written explanation to applicant whose privileges are denied or limited, and reporting to Hospital Licensing Board credentialing decisions based substantially on economic factors to study effects such decisions have on access to care and availability of physician services).

n157. Dahl, supra note 153, at 303.

n158. See *Rao v. Bd. of County Comm'rs, 497 P.2d 591, 593 (Wash. 1972)* (stating that public interest is "the most vital interest in the quality of medical care received in a hospital").

n159. *Sosa v. Bd. of Managers, 437 F.2d 173, 177 (5th Cir. 1971);* accord *Branch v. Hempstead County Mem'l Hosp., 539 F. Supp. 908, 918 (W.D. Ark. 1982)* (supporting a limited judicial role and deference to board decisions); *Smith v. Our Lady of the Lake Hosp., Inc., 639 So. 2d 730, 742 (La. 1994)* (recognizing and deferring to expert skill of medical community to police itself); *Campbell v. St. Mary's Hosp., 252 N. W.2d 581, 587 (Minn. 1977)* (interpreting Minnesota statute as encouraging self-policing of medical profession); *Wong v. Garden Park Cmty. Hosp., Inc., 565 So. 2d 550, 553 (Miss. 1990)* (interpreting Mississippi statute as supporting hospital's right to regulate staff); *Cameron v. New Hanover Mem'l Hosp., Inc., 293 S.E.2d 901, 922 (N.C. Ct. App. 1982)* (determining court should not substitute board's judgment); *Rao v. Auburn Gen. Hosp., 573 P.2d 834, 836 (Wash. Ct. App. 1978)* (finding hospital has discretion to exclude doctors from its staff).

n160. See *Fritz v. Huntington Hosp., 348 N.E.2d 547, 554 (N. Y. 1976)* (stating that "availability of health services is a matter of vital public concern, and hospitals.., direct their best efforts toward ameliorating medical service shortages and increasing the availability of physicians").

n161. See *Holmes v. Hoemako Hosp,, 573 P.2d 477, 479-80 (Ariz. 1977)* (finding opportunity to choose doctor is a public interest); *Silver v. Castle Mem'l Hosp., 497 P.2d 564, 568 (Haw. 1972)* (finding fiduciary duty in hospital's selection of physicians); *Berman v. Valley Hosp., 510 A.2d 673, 676 (N.J. 1986)* (recognizing patient's need to have opportunity to select physician and have access to hospital); *Greisman v.*

Newcomb Hosp., 192 A.2d 817, 824 (N.J. 1963) (recognizing patient of doctor will want to be admitted under own doctor's care).

n162. *Balkissoon v. Capitol Hill Hosp., 558 A.2d 304, 308 (D.C. Cir. 1989)* (quoting *Nanavati v. Burdette Tomlin Mem'l Hosp., 526 A.2d 697, 701 (N.J. 1987)).*

n163. See infra notes 165-68 and accompanying text for a discussion of legislation encouraging peer review of physicians.

n164. Scheutzow, supra note 2, at 7. The credentialing process is only one facet of the broader concept of peer review which also encompasses utilization review, infections review, and the review of specific hospital functions. Arthur F. Southwick & Debra A. Slee, Quality Assurance in Health Care, 5 J. *Legal Med. 343, 344 (1984).*

n165.42 *U.S.C. 11101(3)* (1995) (suggesting that "professional peer review" can help solve the national problem of medical malpractice).

n166. Id. at 11111

n167. See infra note 168 and accompanying text for example of a state statute encouraging peer review as a matter of public policy.

n168. *210 Ill. Comp. Star. Ann. 85/10.2* (West Supp. 2000); 225 *Ill. Comp. Star. Ann. 60/5* (West 1998). For similar pronouncements, see *Cal. Bus. & Prof Code 809(a)(3)* (West 1990) (declaring peer review "essential to preserving the highest standards of medical practice"); *Haw. Rev. Star. Ann. 671D-3* (Michie 1996) (declaring peer review addresses rise in medical malpractice issues). See also *Scappatura v. Baptist Hosp., 584 P.2d 1195, 1200 (Ariz. Ct. App, 1978)* (finding "public policy calls for the intervention by hospital and

medical staffs between physicians and patients in the interests of sound patient care").

n169. See *Van Campen v. Olean Gen. Hosp., 205 N.ES. 554, 555-56 (N.Y. App. Div. 1924)* (stating that public hospitals are instrumentalities of state), affd, *147 N.E. 219 (N. Y. 1925).*

n170. *Id. at 555.* Accord *Shulman v. Washington Hosp. Ctr., 222 F. Supp. 59, 61 (D.D.C. 1963)* (stating that public hospitals are supported by government funds and are managed by the government); *Edson v. Griffin Hosp., 144 A.2d 341, 343 (Conn. Super. Ct. 1958)* (noting that city hospitals are public institutions, owned by public and devoted to public); *Hughes v. Good Samaritan Hosp., 158 S.W.2d I59, 161 (Ky. 1942)* (citing Van Campen as authority for proposition that public hospitals are publicly funded and operated); *Levin v. Sinai Hosp., Inc., 46 A.2d 298, 300 (Md. 1946)* (noting that public corporations are funded and maintained by government).

n171. *Shulman, 222 F. Supp. at 61.*

n172. See, e.g., *Yashon v. Hunt, 825 F.2d 1016, 1022 (6th Cir. 1987)* (considering procedural due process violations); *Sosa v. Bd. of Managers, 437 F.2d 173, 174 (5th Cir. 1971)* (considering Fourteenth Amendment violations); *Campbell v. St. Mary's Hosp., 252 N. W.2d 581, 585 (Minn. 1977)* ("It is of course elementary that the due process provisions of the Fourteenth Amendment and Minn. Const. art. 1, 7, apply only if the actions to terminate plaintiffs surgical privileges were done under color of state law."); *Ritter v. Bd. of Comm'rs, 637 P.2d 940, 944-45 (Wash. 1981)* (considering due process violations); el. *Hayman v. City of Galveston, 273 U.S. 414, 416-17 (1927)* (questioning but assuming that public hospital's actions were limited by Fourteenth Amendment and finding regulation excluding osteopath was not arbitrary nor unreasonable); *Newton v. Bd.*

of Comm'rs, 282 P. 1068, 1070 (Colo. 1929) (following Hayman).

n173. See *Findlay v. Bd. of Supervisors, 230 P.2d 526, 530 (Ariz. 1951)* (holding that public hospital could not terminate physician privileges based on unconstitutional resolution); *Ware v. Benedikt, 280 S. W.2d 234, 236 (Ark. 1955)* (stating that doctors may not be denied privileges based on unreasonable or arbitrary rules); *Hamilton County Hosp. v. Andrews, 84 N.E.2d 469, 471 (Ind. 1949)* (noting that physicians may not be discriminated against by county hospital); *Alpert v. Bd. of Governors, 145 N. Y.S.2d 534, 537-39 (N. Y. App. Div. 1955)* (stating that physicians may not be kept out of public hospitals by operation of unreasonable rules); *Henderson v. City of Knoxville, 9 S. W.2d 697, 698 (Tenn. 1928)* (stating that public hospitals may not enforce regulations that violate state law against doctors); *Johnson v. City of Ripon, 47 N. W.2d 328, 330 (Wis. 1951)* (stating that public hospitals may not enforce unreasonable regulations pertaining to physician privileges).

n174. See, e.g., *Owens v. New Britain Gen. Hosp., 643 A.2d 233, 239 n.24 (Conn. 1994)* (noting private hospital action not state action and, thus, not subject to constitutional compliance); *Adkins v. Sarah Bush Lincoln Health Ctr., 544 N.E.2d 733, 739 (Ill. 1989)* (noting private hospital's acts not subject to due process considerations); *Babcock v. St. Francis Med. Ctr., 543 N. W.2d 749, 759 (Neb. Ct. App. 1996)* (establishing lack of state action by private hospital insulates hospital's decisions from constitutional scrutiny); *Bouquett v. St. Elizabeth Corp., 538 N.E.2d 113, 116 (Ohio 1989)* (stating appellee's failure to show state action by private hospital destroyed his constitutional claim).

n175.17 *U.S. (4 Wheat.) 518 (1819).*

n176. Id. at 668-69.

n177. "No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, 1.

n178. See infra notes 178-83 and accompanying text for examples of Supreme Court's adherence to the holding that the 14th Amendment applies only to state action.

n179. *419 U.S. 345 (1974).*

n180. *Jackson, 419 U.S. at 349* (citing Shelley v. Kramer, 334 U.S. (1949)).

n181.500 *U.S. 614 (1991).*

n182. *Edmonson, 500 U.S. at 619* (quoting *Lugar v. Edmonson Oil Co., 457 U.S. 922, 936-37 (1982)).*

n183. *Edraonson, 500 U.S. at 619* (citations omitted).

n184. One commentary describing the state of the law at the time of its writing noted: "Since most courts are unyielding in their application of the sound discretion rule, often the only question in these cases is whether the hospital is public or private." Note, The Physician's Right to Hospital Staff Membership: The Public-Private Dichotomy, *1966 Wash. U. LQ. 485, 492 n.29 (1966).*

n185. See, e.g., *Pariser v. Christian Health Care Sys., Inc., 816 F.2d 1248, 1252 (8th Cir. 1987)* (noting plaintiff alleged private hospital's actions constituted state action); *Babcock v. St. Francis Med. Ctr., 543 N.W.2d 749, 759 (Neb. Ct. App. 1996)* (reciting plaintiffs argument that private hospital "was a public or quasi-public entity and thus that its actions were state actions"); *Mahmoodian v. United Hosp. Ctr., Inc.,*

404 S.E.2d 750, 752 n.2 (W. Va. 1991) (noting plaintiff argued that private hospital was "state actor").

n186. See, e.g., *Levin v. Sinai Hosp., Inc., 46 A.2d 298, 300-01 (Md. 1946)* (holding hospital was private corporation even though "engaged in charitable work" and "operated solely for the benefit of the public"); *Van Campen v. Olean Gen. Hosp., 205 N.ES. 554, 556 (N.Y. App. Div. 1924)* ("That they are engaged in charitable work for the benefit of the public, and thereby affected with a public interest, does not make them public corporations."), affd, *147 N.E. 219 (N. Y. 1925).*

n187. The Hill-Burton Act, *42 U.S.C. 291* (1996).

n188. See, e.g., *Babcock, 543 N. W.2d at 759* (noting receipt of Medicaid and Medicare funds); *Van Campen, 205 N.Y.S. at 556* ("The fact that they may receive a donation from the government to enable them to carry on their work, or funds from a city or county to care for sick, disabled indigent persons, does not affect their character as private institutions."); *Mahmoodian, 404 S.E.2d at 752 n.2* (noting receipt of "funds from governmental sources").

n189. See *Van Campen, 205 N.Y.S. at 556* (holding exemption from liability for negligence to patients did not affect status). With the widespread abrogation of charitable immunity, this justification has disappeared. See supra notes 115-18 and accompanying text for a discussion of the abrogation of charitable immunity.

n190. See, e.g., *Pariser, 816 F.2d at 1252* (holding enjoyment of tax benefits did not amount to state action); *Babcock, 543 N. W.2d at 759* (holding use of tax-free bonds and tax exemption, among other factors, insufficient to establish state action); *Van Campen, 205 N. Y.S. at 556* (holding tax exemption did not affect status).

n191. See, e.g., *Pariser, 816 F.2d at 1252* (holding subjection to pervasive governmental regulation insufficient to establish state action); *Mahmoodian, 404 S.E.2d at 752 n.2* (holding subjection to governmental regulation insufficient).

n192. See, e.g., *Pariser, 816 F.2d at 1252* (holding list of government-related factors did not make a private hospital into a public one); *Mendez v. Belton, 739 F.2d 15, 17-18 (1st Cir. 1984)* (finding panoply of factors did not change hospital's status from private to public); *Loh-Seng Yo v. Cibola Gen. Hosp., 706 F.2d 306, 308 (l Oth Cir. 1983)* (holding plaintiffs cause of action properly dismissed because he had failed to prove that government funding of private hospital changed its private status); *Hodge v. Paoli Mem'l Hosp., 576 F.2d 563, 564 (3d Cir. 1978)* (affirming lower court's dismissal of case because list of government-related factors did not make private hospital into a state actor); *Schlein v. Milford Hosp., Inc., 561 F.2d 427, 428-29 (2d Cir. 1977)* (stating that although private hospital had substantial ties to state, it remained private); *Madry v. Sorel, 558 F.2d 303, 305 (5th Cir. 1977)* (holding that private hospital's use of state land and money did not make it state actor); *Briscoe v. Bock, 540 F.2d 392, 395-96 (8th Cir. 1976)* (holding that government involvement in private hospital did not make it state actor); *Watkins v. Mercy Med. Ctr., 520 F.2d 894, 896 (9th Cir. 1975)* (dismissing plaintiffs case because he had failed to show state involvement in actions of private hospital named as defendant); *Jackson v. Norton-Children's Hosps., Inc., 487 F.2d 502, 502-03 (6th Cir. 1973)* (affirming lower court dismissal of case against private hospital because hospital was private corporation); *Doe v. Bellin Mem'l Hosp., 479 F.2d 756, 761-62 (7th Cir. 1973)* (deciding plaintiff had no cause of action against private hospital because hospital was not acting under color of state law); *Ward v. St. Anthony Hosp., 476 F.2d 671, 674 (lOth Cir. 1973)* (stating private hospital's receipt of federal funds did not make it state actor); *Canady v. Providence Hosp., 903 F. Supp. 125, 126-27 (D.D.C. 1995)*

(noting private hospital's receipt of federal funds did not make it subject to federal constitutional law), affd, *132 F.3d 1480 (D. C. Cir. 1997); Brandt v. St. Vincent Infirmary, 701 S. W.2d 103, 105-06 (Ark. 1985)* (holding private hospital's actions not governed by 14th Amendment even though hospital received government funds); *Bello v. South Shore Hosp., 429 N.E.2d 1011, 1014 (Mass. 1981)* (holding private hospital's actions not performed under color of state law); *Babcock v. St. Francis Med. Ctr., 543 N.W.2d 749, 759 (Neb. Ct. App. 1996)* (holding array of factors did not support determination that private hospital was public institution); *Mahmoodian v. United Hosp. Ctr., Inc., 404 S.E.2d 750, 752 n.2 (W. Va. 1991)* (noting private hospital not state actor or subject to due process requirements); *Fletcher v. Eagle River Mem'l Hosp., Inc., 456 N. W.2d 788, 797 (Wis. 1990)* (stating plaintiff's claim of private hospital's receipt of government funds did not make it state actor). For early cases, see, for example, *Edson v. Griffin Hosp., 144 A.2d 341, 343-44 (Conn. Super. Ct. 1958)* (stating private hospital's receipt of state aid did not make hospital public); *West Coast Hosp. Ass'n v. Hoare, 64 So. 2d 293, 296-97 (Fla. 1953)* (stating private hospital was private corporation despite government involvement in some hospital affairs); *Levin v. Sinai Hosp., Inc., 46 A.2d 298, 300-01 (Md. 1946)* (stating private hospital not public even though it performed charitable work and was opened for use by public); *Van Campen v. Olean Gen. Hosp., 205 N.Y.S. 554, 556 (N. Y. App. Div. 1924)* (noting government contributions to private hospital did not change hospital's status to public), aff'd, *147 N.E. 219 (N. Y. 1925).*

Initially, the Fourth Circuit held that such factors did support a finding of state action. See *Sams v. Ohio Valley Gen. Hosp. Ass'n, 413 F.2d 826, 828 (4th Cir. 1969)* (explaining that receipt of Hill-Burton funds make private hospital constrained by Federal Constitution); *Simkins v. Moses H. Cone Mem'l Hosp., 323 F.2d 959, 967-68 (4th Cir. 1963)* (noting participation in Hill-Burton program makes hospital state actor, subject to constitutional commands). In 1982, the

Fourth Circuit reversed itself in light of Supreme Court precedent in *Jackson v. Metropolitan Edison Co., 419 U.S. 345 (1974)* and subsequent decisions. See *Modaber v. Culpeper Mem'l Hosp., Inc., 674 F.2d 1023, 1025-26 (4th Cir. 1982)* (holding receipt of Hill-Burton funds by private hospital does not make it state actor). See also *Mahmoodian, 404 S.E.2d at 752 n.2* (recognizing overruling of earlier line of cases).

A few courts, however, have viewed these factors as supporting a third classification of hospitals - "quasi-public" hospitals. Based on this finding, those courts have justified greater judicial review and have treated quasi-public hospitals much the same as public hospitals. See *Kiester v. Humana Hosp. Alaska, Inc., 843 P.2d 1219, 1223 n.2 (Alaska 1992)* (reiterating that private hospital classified as quasi-public when it received government money); *Storrs v. Lutheran Hosps. & Homes Soc'y, Inc., 609 P.2d 24, 28 (Alaska 1980)* (holding private hospital "quasi-public" and must afford due process); *Brandt v. St. Vincent Infirmary, 701 S. W.2d 103, 107-08 (Ark. 1985)* (Dudley, J., concurring) (stating private hospital quasi-public and, therefore, required to afford doctors due process); *Silver v. Castle Mem'l Hosp., 497 P.2d 564, 570 (Haw. 1972)* (noting receipt of government funds demanded private hospital comply with due process standards); cf. *Allison v. Centre Cmty. Hosp., 604 A.2d 294, 297 (Pa. Commw. Ct. 1992)* (discussing quasi-public hospital category, but holding that all hospitals should be treated same).

n193. See infra notes 194-238 and accompanying text for a discussion of "rule of nonreview."

n194. See *G ianetti v. Norwalk Hosp., 557 A.2d 1249, 1255-56 (Conn. 1989)* (recognizing nonreview doctrine but declining to apply it to contractual dispute); *Barrows v. Northwestern Mem'l Hosp., 525 N.E.2d 50, 52 (Ill. 1988)* (adhering to doctrine of nonreview). See also *Samuel v.*

Herrick Mem'l Hosp., 201 F.3d 830, 835 (6th Cir. 2000) (applying "nonreviewability rule"); *Mahmoodian vo United Hosp. Ctr., Inc., 404 S.E.2d 750, 755 n.8 (W. Va. 1991)* (detailing jurisdictions adopting and sources discussing doctrine of nonreview); Groseclose, supra note 92, at 10-11 (discussing rule of nonreview).

n195. *Shulman v. Washington Hosp. Ctr., 222 F. Supp. 59, 63 (D.D.C. 1963);* accord *Hoffman v. Garden City Hosp.-Osteopathic, 321 N. W.2d 810, 813 (Mich. Ct. App. 1982)* (quoting Shulman); *Sarin v. Samaritan Health Ctr., 440 N. W.2d 80, 82 (Mich. Ct. App. 1989)* (quoting Hoffman and Shulman); *Winston v. American Med. Int'l, Inc., 930 S. W.2d 945, 956 (Tex. Ct. App. 1996)* (citing numerous Texas cases that private hospital's decision not subject to review); *Tigua Gen. Hosp., Inc. v. Feuerberg, 645 S. W.2d 575, 578 (Tex. Ct. App. 1982)* (finding decision of private hospital nonreviewable).

n196. See, e.g., *Moore v. Andalusia Hosp., Inc., 224 So. 2d 617, 619 (Ala. 1969)* (concluding private hospital decisions not subject to review); *Scappatura v. Baptist Hosp., 584 P.2d 1195, 1199 (Ariz. Ct. App. 1978)* (declaring no judicial review unless hospital violated bylaws); *Barrows v. Northwestern Mem'l Hosp., 525 N.E.2d 50, 51-55 (Ill. 1988)* (refusing to follow trend of judicial review); *Pepple v. Parkview Mem'l Hosp., Inc., 536 N.E.2d 274, 276 (Ind. 1989)* (declaring review only allowed if sufficient nexus exists between private hospital and state); *Long v. Chelsea Cmty. Hosp., 557 N. W.2d 157, 161-62 (Mich. Ct. App. 1996)* (adopting limited rule of nonreview in contract cases); *Sarin v. Samaritan Health Ctr., 440 N. W.2d 80, 82 (Mich. Ct. App. 1989)* (adopting rule of nonreview for private hospital); *Medical Ctr. Hosps. v. Terzis, 367 S.E.2d 728, 730 (Va. 1988)* (declaring merits of hospital's conclusions nonreviewable); *Mahmoodian v. United Hosp. Ctr., Inc., 404 S.E.2d 750, 755 & n.8 (W. Va. 1991)* (declaring support of nonreview in case law). See also *Hottentot v. Mid-Maine Med. Ctr., 549 A.2d 365, 368-69 (Me. 1988)* (following

rule of nonreview but suggesting on different facts it might reconsider the rule).

n197. See infra notes 194-282 for a discussion of the history of the rule of nonreview and its limitations.

n198. *Anonymous, 90 Eng. Rep. 331 (K.B. 1687).*

n199. See, e.g., *People ex rel. Replogle v. Julia F. Burnham Hosp., 71 Ill. App. 246, 249-50 (1897)* (finding fully within hospital's power to adopt bylaws that are reasonable and consistent with general purposes of the corporation); *Harris v. Thomas, 217 S. W. 1068, 1076-77 (Tex. Civ. App. 1920)* (arguing that courts of equity generally will not interfere with decisions of voluntary associations); cf. *Hayman v. City of Galveston, 273 U.S. 414, 417 (1927)* (involving public hospital and allowing regulation excluding osteopath where regulation was not arbitrary or unreasonable).

n200. See *Replogle, 71 Ill. App. at249-50; Van Campen v. Olean Gen. Hosp., 205 N.Y.So 554, 557(N.Y. App. Div. 1924)* (utilizing general corporation law to justify deference to board's decision), affd, *147 N.E. 219 (N. Y. 1925).*

n201. *Replogle, 71 Ill. App. at 250.*

n202. *217 S. W. 1068 (Tex. Civ. App. 1920).*

n203. *193 N.W. 994 (Wis. 1923).*

n204. *Harris, 217S.W. at 1069-70.*

n205. *Id. at 1074.*

n206. *Id. at 1076o77.*

n207. *ld. at 1077.*

n208. *Id. at 1078.*

n209. *193 N.W. 994 (Wis. 1923).*

n210. *Wolf 193 N.W. at 995.*

n211. *Id. at 995-96.*

n212. *Id. at 996.* See also *Johnson v. City of Ripon, 47 N. W.2d 328, 329-30 (Wis. 1951)* (contrasting private hospital with public hospital and acknowledging Wolt's holding that private hospitals have right to exclude physicians).

n213. *Wolf, 193 N.W. at 996.*

n214. *205 N.ES. 554 (N.E App. Div. 1924),* affd, *147 N.E. 219(N.Y. 1925).*

n215. *Van Campen, 205 N.ES. at 556.*

n216. *Id. at 558.*

n217. *ld. at 555.*

n218. *Id. at 556.*

n219. *Id. at 557-58.* See also *Alpert v. Bd. of Governors, 145 N.Y.S.2d 534, 538-39 (N. Y. App. Div. 1955)(citing* Van Campen, contrasting public hospital with private hospital, and holding that public hospital may not arbitrarily or unreasonably exclude physician).

n220. *194 S.E. 65 (S.C. 1937).*

n221. *Strauss, 194 S.E. at65.*

n222. Id.

n223. Id.

n224. *Van Campen v. Olean Gen. Hosp., 205 N.Y.S. 554 (N.Y. App. Div. 1924),* affd, *147 N.E. 219 (N.Y. 1925). See* supra notes 214-19 and accompanying text for a discussion of Van Campen.

n225. *158 S. W.2d 159 (Ky. 1942).*

n226. *Hughes, 158 S. W.2d at 160.*

n227. *Id. at 161-62.*

n228. *Id. at 162.*

n229.46 *A.2d 298 (Md. 1946).*

n230. *Levin, 46 A.2d at 300-01.*

n231. *Id. at 303, 301.*

n232.52 *N.W.2d 701 (Iowa 1952).*

n233. *Natale, 52 N. W.2d at 704.*

n234. *Id. at 706.*

n235. *Id. at 707.*

n236. Id.

n237. *Id. at 709.*

n238. *Natale, 52 N. W.2d at 709.* See infra notes 414-25 and accompanying text for a discussion of the distinction between hospital bylaws and medical staff bylaws. For other early courts following the rule of nonreview see, e.g, *Shulman v. Washington Hosp. Ctr., 222 F. Supp. 59, 63 (D.D.C.*

1963) (embracing the rule of nonreview); *Edson v. Griffin Hosp., 144 A.2d 341, 345 (Conn. Super. Ct. 1958)* (recognizing general rule that hospitals, like corporations, have right to regulate affairs without interference); *West Coast Hosp. Ass'n v. Hoare, 64 So. 2d 293, 297 (Fla. 1953)* (determining non-profit corporation has right to manage own affairs).

n239. *Van Campen v. Olean Gen. Hosp., 205 N.Y.S. 554, 556 (N.Y. App. Div. 1924)*, affd, *147 N.E. 219 (N.Y. 1925).*

n240. *State ex rel. Wolf, 193 N.W. 994, 996 (Wis. 1923).*

n241. *Levin v. Sinai Hosp. of Baltimore City, Inc., 46 A.2d 298, 301 (Md. 1946).* See infra notes 414-25 and accompanying text for a discussion of the distinction between hospital bylaws and medical staff bylaws.

n242. *Natale, 52 N. W.2d at 709.*

n243. Id.

n244. *121 A. 475 (Md. 1923).*

n245. *Stevens, 121 A. at 476.*

n246. *Id. at 475-76.*

n247. *Id. at 476-77.*

n248. *Id. at 478-79.* See also *Emergency Hosp. v. Stevens, 126 A. 101, 103 (Md. 1924)* (discussing injunction).

n249. *Van Campen v. Olean Gen. Hosp., 205 N.ES. 554 (N.Y. App. Div. 1924)*, affd, *147 N.E. 219(N.Y. 1925). See* supra notes 216-21 and accompanying text for a discussion of Van Campen.

n250. *Levin v. Sinai Hosp. Inc., of Baltimore City, 46 A.2d 298 (Md. 1946).* See supra notes 229-31 and accompanying text for a discussion of Levin.

n251. Natale v. Sisters of Mercy, 52 N. W.2d 701 (Iowa 1952). See supra notes 232-38 and accompanying text for a discussion of Natale.

n252. In *Glass v. Doctors Hospital Inc., 131 A.2d 254 (Md. 1957), the* Maryland Supreme Court viewed refusal to renew privileges as an exclusion case rather than a dismissal case. *Id. at 263.* Consequently, the medical staff bylaws notice and hearing requirements, necessary for dismissal, did not apply. Id. The court held that the physician "was merely notified that his year to year privileges would not be renewed when they expired. In such case no notice, other than that given him, and no hearing are required." Id.

n253. *Natale v. Sisters of Mercy, 52 N.W.2d 701, 704 (Iowa 1952).* See also *Levin v. Sinai Hosp., 46 A.2d 298, 303 (Md. 1946)* (involving no limitation on privileges); *Van Campen v. Olean Gen. Hosp., 205 N.Y.S. 554, 555 (N. Y. App. Div. 1924)* (involving limitation on existing privileges), affd, *147 N.E. 219 (N. Y. 1929).*

n254. See *Adkins v. Sarah Bush Lincoln Health Ctr., 544 N.E.2d 733, 737-38 (Ill. 1989)* (finding exception to nonreview rule when privileges pre-existing). See also *Chessick v. Sherman Hosp. Ass'n, 546 N.E.2d 1153, 1156 (Ill. App. Ct. 1989)* (finding exception where privileges pre-existing and where hospital failed to follow bylaws); *Claydon v. Sisters of the Third Order of St. Francis, 536 N.E.2d 209, 210-11 (Ill. App. Ct. 1989)* (referring to "limitation" of general rule). But see *Medical Ctr. Hosp. v. Terzis, 367 S.E.2d 728, 730 (Va. 1988)* (finding no difference between refusal to grant privileges and suspension of privileges).

n255. See, e.g., *Balkissoon v. Capitol Hill Hosp., 558 A.2d 304, 307 (D.C. Cir. 1989)* (stating "hospital must still afford appellant at least all of the process and protections encompassed in its bylaws"); *Adkins v. Sarah Bush Lincoln Health Ctr., 544 N.E.2d 733, 739, 741 (Ill. 1989)* (stating "basic protections include notice and a fair hearing"); *Babcock v. St. Francis Med. Ctr., 543 N. W.2d 749, 759 (Neb. Ct. App. 1996)* (allowing review to determine compliance and fairness); *Brinton v. IHC Hosps., Inc., 973 P.2d 956, 964 (Utah 1998)* (limiting review to fairness of peer review and compliance with bylaws); *Mahmoodian v. United Hosp. Ctr., Inc., 404 S.E.2d 750, 755 (W. Va. 1991)* (limiting review to compliance with bylaws, fair hearing, and notice).

n256. As one might expect, probably a majority of the reported cases are an application of the "exception" and not the rule. Of course it is not surprising that the part of the rule which allows judicial review would be more prevalent in reported cases than the part of the rule denying review.

n257. See infra notes 283-303 and accompanying text for a discussion of the contract theory for judicial review and decisions affecting existing staff membership or clinical privileges.

n258. *Van Campen v. Olean Gen. Hosp., 205 N.ES. 554, 557(N.Y. App. Div. 1924)*, aff'd, *147 N.E. 219(N.Y. 1929).*

n259. But see *Loewinthan v. Beth David Hosp., 9 N. Y.S.2d 367, 370 (N. Y. Sup. Ct. 1938)* (holding allegation that hospital violated its bylaws in dismissing physician insufficient where no contractual relationship shown).

n260. *Levin v. Sinai Hosp. of Baltimore City, Inc., 46 A.2d 298, 301 (Md. 1946).*

n261. 222 F. *Supp. 59 (D.D.C. 1963).*

n262. *Shulman, 222 F. Supp. at 63.*

n263. See *Hongsathavij v. Queen of Angels/Hollywood Presbyterian Med. Ctr., 73 Cal. Rptr. 2d 695, 699 n.2 (Cal. Ct. App. 1998)* (stating that medical staff is separate legal entity, an unincorporated association); *Corleto v. Shore Mem'l Hosp., 350 A.2d 534, 539 (N.J. Super Ct. 1975)* (concluding medical staff is unincorporated association capable of being sued); *Manczur v. Southside Hosp., 183 N. Y.S. 2d 960, 961-62 (N. Y. Sup. Ct. 1959)* (holding medical staff is unincorporated association); *St. John's Hosp. Med. Staff v. St. John Reg'l Med. Ctr., 245 N.W.2d 472, 474 (S.D. 1976)* (finding medical staff is unincorporated association with standing to bring declaratory judgment action). See also Isele, supra note 68, at 3-4 (stating medical staff is separate legal entity, usually an unincorporated association). See infra notes 414-25 for a discussion of the distinction between a hospital and its medical staff.

n264. *Van Campen v. Olean Gen. Hosp., 205 N.ES. 554, 557(N.Y. App. Div. 1924),* affd, *147 N.E. 219(N.Y. 1929).* See supra notes 214-19 and accompanying text for a discussion of Van Campen.

n265. *Levin v. Sinai Hosp., 46 A.2d 298, 301 (Md. 1946).* See supra notes 229-31 and accompanying text for a discussion of Levin.

n266. *Shulman v. Washington Hosp. Ctr., 222 F. Supp. 59 (D.D.C. 1963).* See supra notes 261-62 and accompanying text for a discussion of Shulman.

n267. *Natale v. Sisters of Mercy, 52 N.W.2d 701, 709 (Iowa 1952).* See infra notes 413-47 and accompanying text for a discussion of the distinction between the hospital and medical staff and whether the medical staff bylaws should be binding on the hospital.

n268. See *Barrows v. Northwestern Mem'l Hosp., 525 N.E.2d 50, 55 (Ill. 1988)* (declining to review hospital's refusal to make staff appointment); *Bello v. South Shore Hosp., 429 N.E.2d 1011, 1016 (Mass. 1981)* (finding no support for proposition that non-staff members have a right to challenge application of the bylaws); *Mahmoodian v. United Hosp. Ctr. Inc., 404 S.E.2d 750, 755 (W. Va. 1991)* (allowing review involving existing privileges).

n269. See *Sarin v. Samaritan Health Cir., 440 N. W.2d 80, 83 (Mich. Ct. App. 1989)* (concluding no review because would involve review of boards substantive decisions). See also *Samuel v. Herrick Mem'l Hosp., 201 F.3d 830, 836 (6th Cir. 2000)* (following Satin and applying "Michigan's flat rule against judicial intervention"); *Long v. Chelsea Cmty. Hosp., 557 N.W.2d 157, 161-62 (Mich. Ct. App. 1996)(following* Sarin).

n270. See *Samuel, 201 F.3d at 834-35 (6th Cir. 2000)* (considering discrimination and antitrust claims but finding no jurisdiction to consider tortious interference with contract claim); *Menkowitz v. Pottstown Mem'l Med. Ctr., 154 F.3d 113, 121 (3d Cir. 1998)* (stating physician may state claim under Americans with Disabilities Act); *Muzquiz v. W.A. Foote Mem'l Hosp., Inc., 70 F.3d 422, 428-30 (6th Cir. 1995)* (applying Michigan law and rejecting breach of contract claim but considering separately and rejecting on facts Title VII and antitrust theories); *Ponca City Hosp. Inc. v. Murphree, 545 P.2d 738, 742 (Okla. 1976)* (supporting judicial review of claims of race, sex, or age discrimination). Antitrust claims are often alleged in staff privileging cases, but they are rarely successful. See Furrow, supra note 116, at 10-16, at 623 & nn.5-7, 10-25 for a good general discussion of antitrust claims.

n271. *557 N.W.2d 157(Mich. Ct. App. 1996).*

n272. *Long, 557 N.W.2d at 161-62.*

n273. See *Cooper v. Delaware Valley Med. Ctr., 654 A.2d 547, 552 (Pa. 1995)* (allowing damages under tort and contract theory arising out of peer review); *Saad v. Sacred Heart Hosp., 700 A.2d 604, 606-07 (Pa. Commw. Ct. 1997)* (finding exception to nonreview where claim based on tort or contract); el. *Rosenberg v. Holy Redeemer Hosp., 506 A.2d 408, 412 (Pa. Super. Ct. 1986)* (stating private hospital's staffing decisions not subject to judicial review).

n274. See Groseclose, supra note 92, at 14 ("A persuasive argument is thereby provided that the distinction between public and private hospitals is abolished and a physician cannot be denied access to either a public or private hospital without constitutional due process."); Karen G. Seimetz, Note, Medical Staff Membership Decisions: Judicial Intervention, *1985 U. Ill. L. Rev. 473, 483-84* (finding little difference between public and private hospitals and arguing impact of unfair staffing decision the same). See also *Kiester v. Humana Hosp. Alaska, Inc., 843 P.2d 1219, 1223 n.2 (Alaska 1992)* (noting trend affording judicial review so that no hospital, public or private, adopts rule that exclude arbitrary or capriciously); *Storrs v. Lutheran Hosps. & Homes Soc'y, Inc., 609 P.2d 24, 28 (Alaska 1980)* (holding private hospital "quasi-public" and must afford due process because it was only hospital serving community and enjoyed significant government funding); *Brandt v. St. Vincent Infirmary, 701 S. W.2d 103, 107 (Ark. 1985)* (Dudley, J., concurring) (arguing private hospital should be considered "quasi-public"); *Mahmoodian v. United Hosp. Ctr., Inc., 404 S.E.2d 750, 752 (W. Va. 1991)* (finding public/private dichotomy distracting from more significant issues; noting scope of judicial review essentially the same for both private and public hospitals); Of. *Silver v. Castle Mem'l Hosp., 497 P.2d 564, 570 (Haw. 1972)* (stating if fiduciary trust view accepted, public/private/quasi-public distinction "becomes meaningless").

n275. Groseclose, supra note 92, at 3-4.

n276. Seimetz, supra note 274, at 483-84.

n277. Id. at 501.

n278. See *Edmonson v. Leesville Concrete Co., Inc., 500 U.S. 614, 619 (1991)* (stating constitutional limits generally not applicable to private entities); *Jackson v. Metropolitan Edison Co., 419 U.S. 345, 349 (1974)* (holding private conduct not subject to Fourteenth Amendment scrutiny).

n279. See infra Part III.A.4 for a discussion of courts rejecting public/private distinction.

n280. See infra Part III.B for a discussion of courts using a contract theory to reject the public/private distinction.

n281. See infra Part III.C for a discussion of courts' use of common law and public policy theories to impose more extensive judicial review.

n282. See infra Part III.D for a discussion of courts' use of state statutes to define the scope of judicial review.

n283. See infra Part III.B.1 for a discussion of view that medical staff bylaws constitute a contract between a physician and the hospital.

n284. See infra Part III.B.1 for a discussion of courts' view that bylaws create an enforceable contract between a physician and a hospital.

n285. See, e.g., *Babcock v. St. Francis Med. Ctr., 543 N.W.2d 749, 760 (Neb. Ct. App. 1996)* (noting "obligation to follow its own bylaws can stem from a contractual

relationship"); *Brinton v. IHC Hosps., Inc., 973 P.2d 956, 964 (Utah 1998)* (limiting review to breach of contract based on bylaws).

n286. See supra note 256 and accompanying text for a discussion of the exclusion/expulsion distinction.

n287. See *Bello v. South Shore Hosp., 429 N.E.2d 1011, 1016 (Mass. 1981)* (stating physician applicant had no standing to challenge compliance with bylaws); Groseclose, supra note 92, at 25-26 & n. 169 (discussing nature of physician's relationship with hospital). But see infra note 346-64 and accompanying text for argument that applicants should have contractual rights.

n288. See *Pariser v. Christian Health Care Sys., Inc., 816 F.2d 1248, 1251 (8th Cir. 1987)* (applying Illinois law); *Janda v. Madera Cmty. Hosp., 16 F. Supp. 2d 1181, 1184-89 (E.D. Cal. 1998)* (predicting California law); *Islami v. Covenant Med. Ctr., Inc., 822 F. Supp. 1361, 1370-71 (N.D. Iowa 1992)* (predicting Iowa law); *Posner v. Lankenau Hosp., 645 F. Supp. 1102, 1106 (E.D. Pa. 1986)* (finding bylaws create contract between hospital and doctor); *Eidelson v. Archer, 645 P.2d 171, 178 (Alaska 1982)* (holding bylaws form part of contract); *Samaritan Health Sys. v. Superior Court, 981 P.2d 584, 588 (Ariz. Ct. App. 1998)* (holding bylaws create contract); *Bock v. John C. Lincoln Hosp., 702 P.2d 253, 258 (Ariz. Ct. App. 1985)* (finding parties agree bylaws create contract); *Greenberg v. Mount Sinai Med. Ctr., Inc., 629 So. 2d 252, 257 (Fla. Dist. Ct. App. 1993)* (finding bylaws, if approved by governing board, create contract); *Lawler v. Eugene Wuesthoff Mem'l Hosp. Ass'n, 497 So. 2d 1261, 1264 (Fla. Dist. Ct. App. 1986)* (following majority view that bylaws, approved by governing board, create binding contract); *Garibaldi v. Applebaum, 653 N.E.2d 42, 45 (Ill. App. Ct. 1995)* (declaring bylaws part of contractual relationship); *Pepple v. Parkview Mem'l Hosp., Inc., 536 N.E.2d 274, 276 (Ind. 1989)* (agreeing with lower court that bylaws can constitute

contract); *Terre Haute Reg 'l Hosp., Inc. v. El-lssa, 470 N.E.2d 1371, 1377 (Ind. Ct. App. 1984)* (holding bylaws can constitute contract); *Bartley v. Eastern Maine Med. Ctr., 617 A.2d 1020, 1021 (Me. 1992)* (agreeing bylaws create enforceable contract); *Bhatnagar v. Mid-Maine Med. Ctr., 510 A.2d 233, 234 (Me. 1986)* (finding bylaws create enforceable contract); *Anne Arundel Gen. Hosp., Inc. v. O'Brien, 432 A.2d 483, 488 (Md. Ct. Spec. App. 1981)* (finding it "well settled" bylaws create enforceable contract); *Campbell v. St. Mary's Hosp., 252 N.W.2d 581, 586-87 (Minn. 1977)* (concluding under bylaws doctor entitled to "contractual due process rights"); *Babcock v. St. Francis Med. Ctr., 543 N. W.2d 749, 760 (Neb. Ct. App. 1996)* (determining obligation to follow bylaws stems from contractual relationship); *Joseph v. Passaic Hosp. Ass'n, 118 A.2d 696, 700 (N.J. Super Ct. App. Div. 1955)* (finding breach of contract based on hospital's constitution and bylaws); *Falk v. Anesthesia Assocs. of Jamacia, 644 N. Y.S.2d 237, 239-40 (No Y. App. Div. 1996)* (rejecting contention that bylaws do not create contract); *Chuz v. St. Vincent's Hosp., 589 N.Y.S.2d 17, 18 (N.Y. App. Div. 1992)* (acknowledging bylaws may create contract); *Virmani v. Presbyterian Health Servs. Corp., 488 S.E.2d 284, 287-88 (N.C. Ct. App. 1997)* (holding if offer and acceptance contemplated within bylaws, contract exists); *Berberian v. Lancaster Osteopathic Hosp. Ass'n, Inc., 149 A.2d 456, 458-59 (Pa. I959)* (finding directors' approval of bylaws resulted in contractual relationship between hospital and staff); *Miller v. Indiana Hosp., 419 A.2d 1191, 1193 (Pa. Super Ct. 1980)* (stating "bylaws of a hospital constitute the terms of a legally binding contract"); *Lyons v. St. Vincent Health Ctr., 731 A.2d 206, 210-11 (Pa. Commw. Ct. 1999)* (concluding bylaws part of contract between doctor and hospital); *St. John's Hosp. Med. Staff v. St. John Reg'l Med. Ctr., Inc., 245 N. W.2d 472, 474 (S.D. 1976)* (finding, through analogy to corporate bylaws, hospital bylaws create contract); *Lewisburg Cmty. Hosp., Inc. v. Alfredson, 805S. W.2d 756, 759 (Tenn. 1991)* (agreeing, despite split in jurisdictions, bylaws constitute contract); *East Texas Med. Ctr. Cancer Inst. v.*

Anderson, 991 S.W.2d 55, 62-63 (Tex. Ct. App. 1998) (concluding bylaws create contractual due process rights); *Brinton v. IHC Hosps., Inc., 973 P.2d 956, 966 (Utah 1998)* (discussing contractual obligations under bylaws); *Rees v. Intermountain Health Care, Inc., 808 P.2d 1069, I076-77 (Utah 1991)* (stating bylaws are "in essence, a contract between the hospital and physician"); *Houston v. Intermountain Health Care, Inc., 933 P.2d 403, 408 (Utah Ct. App. 1997)* (agreeing bylaws create contract between hospital and physician); *Mahmoodian v. United Hosp. Ctr., Inc., 404 S.E.2d 750, 755 (W. Va. 1991)* (under breach of contract principles, hospital must follow medical staff bylaws); *Bass v. Ambrosius, 520 N. W.2d 625, 627-29 (Wis. Ct. App. 1994)* (discussing how bylaws create contract). See also *Clemons v. Fairview Med. Ctr., Inc., 449 So. 2d 788, 790 (Ala. 1984)* (breach of contract claim based on violation of medical staff bylaws upheld); *Balkissoon v. Capitol Hill Hosp., 558 A.2d 304, 308 (D. C. Cir. 1989)* (bylaws may create contractual rights); *Clough v. Adventist Health Sys., Inc., 780 P.2d 627, 632 (N.M. 1989)* (accepting district court's holding and parties' assumption that bylaws created implied contract).

Several courts have faced the issue but have not decided it. See *Even v. Longmont United Hosp. Ass'n, 629 P.2d 1100, 1103 (Colo. Ct. App. 1981)* (assuming arguendo that bylaws were contract); *Duby v. Jordan Hosp., 341 N.E.2d 876, 879 (Mass. 1976)* (assuming without deciding that bylaws give rise to contract); *Wong v. Stripling, 700 So. 2d 296, 300-02 (Miss. 1997)* (dismissing breach of contract claim based on violation of bylaws on collateral estoppel grounds); *Gelbard v. Genesee Hosp., 664 N.E.2d 1240, 1242 (N. Y. 1996)* (expressing that question would not be reached until plaintiff exhausted administrative remedies); *Bouquett v. St. Elizabeth Corp., 538 N. E. 2d I 13, I 15-16 (Ohio 1989)* (assuming without deciding that bylaws binding contract); *Ponca City Hosp., Inc. v. Murphree, 545 P.2d 738, 742 (Okla. 1976)* (acknowledging the "bylaws create contract" issue but failing to address it because plaintiff brought suit in equity

seeking injunction); *Medical Ctr. Hosps. v. Terzis, 367 S.E.2d 728, 729 (Va. 1988)* (assuming but expressly not deciding the issue of whether bylaws constitute contracts).

n289. See, e.g., *Gianetti v. Norwalk Hosp., 557 A.2d 1249, 1252-55 (Conn. 1989)* (stating that bylaws are subject to judicial review because they are "an integral part of the contractual relationship" between physician and hospital). See also *Owens v. New Britain Gen. Hosp., 643 A.2d 233, 239 n.25 (Conn. 1994)* (citing Gianetti and finding bylaws create contract).

n290. See, e.g., *Monroe v. AMI Hosp., Inc., 877 F. Supp. 1022, 1029 n.5 (S.D. Tex. 1994)* (interpreting Texas law that bylaws do not constitute contract); *Tredrea v. Anesthesia & Analgesia, P.C., 584 N. W.2d 276, 284-87 (Iowa 1998)* (discussing requirement for bylaws to constitute contract); Sullivan v. Baptist Mem'l Hosp. - *Golden Triangle, Inc., 722 So. 2d 675, 680-81 (Miss. 1998)* (granting privileges does not create contract); *Zipper v. Health Midwest, 978 S. W.2d 398, 415-17 (Mo. Ct. App. 1998)* (holding, in case of first impression, bylaws do not create contract); *Manczur v. Southside Hosp., 183 N. Y.S.2d 960, 961-62 (N. Y. Sup. Ct. 1959)* (finding bylaws created procedural rules for governing staff members not binding contract); *Munoz v. Flower Hosp., 507 N.E.2d 360, 365 (Ohio Ct. App. 1985)* (finding no mutuality of obligation, thus, bylaws do not create contract); *Weary vo Baylor Univ. Hosp., 360 S. W.2d 895, 896-97 (Tex. Civ. App. 1962)* (finding bylaws do not create contract). See also *Robles v. Humana Hosp. Cartersville, 785 F. Supp. 989, 1001 (N.D. Ga. 1992)* (bylaws not contract but enforceable); *St. Mary's Hosp., Inc. v. Radiology Profll Corp., 421 S.E.2d 731, 736 (Ga. Ct. App. 1992)* (holding staff bylaws alone confer no contractual rights but enforceable in tort); *Keskin v. Munster Med. Research Found., 580 N.E. 2d 354, 359 (Ind. Ct. App. 1991)* (finding although bylaws may be contract, not always contract); *Holt v. Good Samaritan Hosp. & Health Ctr., 590 N.E.2d 1318, 1322 (Ohio Ct. App. 1990)*

(finding staff bylaws constitute contract only if intent by both parties to be bound); John Hulston, et al., Do Hospital Medical Staff Bylaws Create a Contract?, *51 J. Mo. B. 352, 355* (Nov./Dec. 1995) (arguing bylaws should not be considered contract giving rise to cause of action for damages, but should be enforceable in action for injunctive relief); Groseclose, supra note 92, at 28 (arguing that "the existence of a contract in this setting is pure fiction"); cf. *Murdoch v. Knollwood Park Hosp., 585 So. 2d 873, 876 (Ala. 1991)* (stating court "not convinced that the hospital bylaws created a binding contract" but not deciding issue); *Todd v. Physicians & Surgeons Cmty. Hosp., Inc., 302 S.E.2d 378, 381 (Ga. Ct. App. 1983)* (noting in dicta district court holding that medical staff bylaws do not constitute contract); *Sarin v. Samaritan Health Ctr., 440 N. W.2d 80, 82 (Mich. Ct. App. 1989)* (refraining from deciding whether bylaws create contract and dismissing breach of contract claim on grounds that court may not review such claim). In *State ex rel. Mississippi Ethics Commission v. Aseme, 583 So. 2d 955 (Miss. 1991), the* Mississippi Supreme Court in a non-credentialing case held that a physician who has been granted staff privileges does not have a contractual relationship with the hospital, *ld. at 960.*

n291.52 *N.W.2d 701 (Iowa 1952).*

n292. See *Gonzalez v. San Jacinto Methodist Hosp., 880 S. W.2d 436, 438-39 (Tex. Ct. App. 1994)* (holding plaintiff physician could have no vested fights stemming from medical staffs bylaws); cf. *lshak v. Fallston Gen. Hosp. & Nursing Ctr., 438 A.2d 1369, 1372 (Md. Ct. Spec. App. 1982)* (noting argument that only hospital bylaws are relevant and not medical staff bylaws); *Tredrea v. Anesthesia & Analgesia, P.C., 584 N. W.2d 276, 284-87 (Iowa 1998)* (distinguishing hospital's bylaws from medical staff bylaws). But see *Lewisburg Cmty. Hosp., Inc. v. Alfredson, 805 S.W.2d 756, 759 (Tenn. 1991)* (rejecting distinction).

n293. *l18 A.2d 696, 700 (N.J. Super Ct. App. Div. 1955).*

n294. *149 A.2d 456 (Pa. 1959).*

n295. *Joseph, 118 A.2d at 697-98.*

n296. *Id. at 698.*

n297. *Id. at 700.*

n298. *Berberian, 149 A.2d at 456.*

n299. *Id. at 458-59.* See also *id. at 459* (physician and hospital had "entered into a contract whereof the provisions of the staff by-laws, as approved by the hospital's board of directors, constitute the legally binding terms"). But see *id. at 461* (Bell, J., dissenting) (stating that staff bylaws not binding on board).

n300. See, e.g., *Centaur Partners, IV v. Nat'l Intergroup, Inc., 582 A.2d 923, 928 (Del. 1990)* (binding board of directors to provisions of bylaws for benefit of shareholders); *In re Estate of Hall, 731 A.2d 617, 623 (Pa. Super. Ct. 1999)* (finding corporate bylaws enforceable upon parties); *Hall v. Tennessee Dressed Beef Co., 957 S.W. 2d 536, 539 (Tenn. 1997)* (finding corporate bylaws enforceable upon parties).

n301. See infra note 302 and accompanying text for a discussion of the reasoning of courts that have found bylaws rendered meaningless if not enforceable.

n302. *Bass v. Arnbrosius, 520 N.W. 625, 627 (Wis. Ct. App. 1994)* (quoting Willaim Shakespeare, Macbeth, act V, scene v, lines 27-28). See also *Lewisburg Cmty. Hosp. v. Alfredson, 805 S.W.2d 756, 759 (Tenn. 1991)* (stating that "to suggest that the hospital has no legal duty to follow its own bylaws would be to reduce the bylaws to meaningless mouthing of words"); *Bouquett v. St. Elizabeth Corp., 538 N.E.2d 113, 115 (Ohio 1989)* (stating "cases holding that a hospital is bound by its staff bylaws base their decisions on

the reasoning that if the hospital is not bound by the bylaws, then essentially the bylaws would be meaningless") (quoting *Munoz v. Flower Hosp., 507 N.E.2d 360, 364 (Ohio Ct. App. 1985)).*

n303. See, e.g., *Zipper v. Health Midwest, 978 S. W.2d 398, 416 (Mo. Ct. App. 1998)* (discussing view that bylaws lack necessary elements to constitute a contract).

n304. *Restatement (Second) of Contracts 1* (1981); accord, e.g., *Cook v. Cook, 691 P.2d 664, 667 (Ariz. 1984)* (stating "sine qua non of any contract is the exchange of promises"); *Atwood v. Western Constr., Inc., 923 P.2d 479, 483 (Idaho Ct. App. 1996)* (defining contract as "a promise or set of promises for the breach of which the law gives a remedy, or the performance of which the law in some way recognizes as a duty"); *Cederstrand v. Lutheran Bhd., 117 N. W.2d 213, 219 (Minn. 1962)* (stating "a contract is a legally enforceable promise); *Fitzpatrick v. Vermont State Treasurer, 475 A.2d 1074, 1077 (Vt. 1984)* (defining special contract as "one with perculiar provisions or stipulations not found in the ordinary contract relating to the same subject matter, and which, if omitted, the law will not supply") (citations omitted)

n305. 1 Joseph M. Perillo, Corbin on Contracts 1.3, at 9 (rev. ed. 1993) (quoting Uniform Commercial Code 1-201).

n306. The authorities are quick to point out that not all enforceable contracts satisfy these requirements. For example, the Restatement (Second) on Contracts recognizes a special category of contracts, "formal contracts," that may be formed without a bargain, manifestation of assent, or consideration. *Restatement (Second) of Contracts 6,* 17 & cmt. a (1981). Even some "atypical" "informal" contracts are binding even though they are not part of a bargain. See id. 17 cmt. e.

n307. See *Ga. Code Ann. 13-3-1* (1982) (stating similar requirements); *Farrington v. Tennessee, 95 U.S. 679, 685 (1877)* (requiring "parties, consent, consideration, and obligation"); *Janda v. Madera Cmty. Hosp., 16 F. Supp. 2d 1181, 1186 (E.D. Cal. 1998)* (requiring consent, lawful object, sufficient cause or consideration, and parties capable of contracting); *Gray v. Reynolds, 514 So. 2d 973, 975 (Ala. 1987)* (requiring agreement, consideration, two or more parties, legal object, and legal capacity); *Westbrook v. Westbrook, 364 S.E.2d 523, 527 (Va. Ct. App. 1988)* (requiring "competent parties, legal subject matter, valuable consideration and mutual consent"); *Restatement (Second) of Contracts 12,* 17 (1981) (requiring capacity and bargaining with mutual assent to contract); 1 Samuel Williston & Richard A. Lord, Williston on Contracts 3:2, at 200-02 (4th ed. 1990) (detailing the requirements for formation of informal contract). See also *Peterson v. Trailways, Inc., 555 F. Supp. 827, 830 (D. Colo. 1983)* (requiring competency of parties, subject matter, legal consideration, mutuality of agreement, mutuality of obligation); *Thomas v. Leja, 468 N. W.2d 58, 60 (Mich. Ct. App. 1991)* (stating essential elements of valid contract include competency of parties, proper subject matter, legal consideration, mutuality of agreement, and mutuality of obligation); *Zipper v. Health Midwest, 978 S. W.2d 398, 416 (Mo. Ct. App. 1998)* (stating essential elements of contract according to Missouri law are competency of parties, proper subject matter, legal consideration, mutuality of agreement, and mutuality of obligation). Some courts identify the elements as offer, acceptance, and consideration. See, e.g., *Tinucci v. R.V. Evans Co., 989 S. W.2d 181, 184 (Mo. Ct. App. 1998)* (noting offer must be "definite" and acceptance must be "unequivocal"). See also *Muchesko v. Muchesko, 955 P.2d 21, 24 (Ariz. Ct. App. 1997)* (requiring offer, acceptance, consideration, sufficiently specific statement of obligations, mutual consent).

The Restatement (Second) of Contracts and other authorities specifically reject the requirement of "mutuality of obligation." See *Restatement (Second) of Contracts 79(c) &* cmt. f (1981) (concluding that if requirement of consideration met, no need for mutuality of obligation); 2 Joseph M. Perillo & Helen Hadjiyannakis Bender, Corbin on Contracts 6.1, at 197 (rev. ed. 1995) (stating "requirement of mutuality of obligation is now widely discredited").

n308. See *Restatement (Second) of Contracts* 22 (1981) (requiring offer and acceptance for assent).

n309. 1 Perillo, supra note 305, 1.1, at 2.

n310. See *Restatement (Second) of Contracts 11* illus. 1 (1981) (illustrating the following example: "A becomes a member of an unincorporated society, and by so doing promises to pay dues to the society. He is bound by a contract."). See also infra notes 414-25 and accompanying text for a discussion of the nature of the medical staff as an entity.

n311. See generally JCAH, Guidelines for Bylaws, supra note 92. See also *Lyons v. St. Vincent Health Ctr., 731 A.2d 206, 210 (Pa. Commw. Ct. 1999)* (explaining hospital's staffing procedures outlined in bylaws); Hulston, et al., supra note 290, at 352. For examples of bylaws see Yale-New Haven Hosp. Bylaws, supra note 92; Presbyterian Hosp. Bylaws, supra note 92; HCWP Model Bylaws, supra note 92; UTMB Bylaws, supra note 92; Oregon Health Sciences University, OHSU Hospital and Clinics and Doernbecher Children's Hospital Bylaws of the Medical Staff Manual (site update Dec. 10, 1999) <http://www.ohsu.edu/hosp-policy/bylaws/bylawsindex.html> [hereinafter "OHSU Bylaws"].

n312. See *Robles v. Humana Hosp. Cartersville, 785 F. Supp. 989, 1001-02 (N.D. Ga. 1992)* (stating bylaws cannot constitute contract because consideration lacking); *Zipper v. Health Midwest, 978 S.W.2d 398, 416 (Mo. Ct. App. 1998)* (concluding bylaws not contract without consideration).

n313. See infra note 315-21 and accompanying text for a discussion of the view that bylaws cannot constitute valid consideration.

n314. *Robles v. Humana Hosp. Cartersville, 785 F. Supp. 989, 1001-02 (N.D. Ga. 1992).* See also *Tredrea v. Anesthesia & Analgesia, P.C., 584 N. W.2d 276, 287 (Iowa 1998)* (refusing to treat by laws as contracts); *Zipper v. Health Midwest, 978 S. W.2d 398, 416 (Mo. Ct. App. 1998)* (holding bylaws not contract because doctors did not give consideration).

n315. *557 A.2d 1249 (Conn. 1989).*

n316. *Gianetti, 557 A.2d at 1253.*

n317. Id.

n318. Id.

n319. See *id. at 1253 n.8* (explaining importance of regulatory commission); JCAHO Manual, supra note 1, MS.2 to MS.2.8 at MS-3 to MS-4 (defining guidelines for adopting bylaws).

n320. See *42 C.F.R. 482.22(c)* (1999) (outlining required content of bylaws and mechanism for adoption).

n321. See *Zipper v. Health Midwest, 978 S.W.2d 398, 416 (Mo. Ct. App. 1998)* (finding consideration lacking where hospital had preexisting legal duty to adopt bylaws). See also *Restatement (Second) of Contracts 73* (1981) ("Performance of a legal duty owed.., is not consideration....").

n322. See infra Part III.D for a discussion of relevant state statutes.

n323. *Restatement (Second) of Contracts* 73 cmt. a, at 180 (1981).

n324. Id. 73.

n325. See *Bass v. Ambrosius, 520 N. W.2d 625, 628 n.8 (Wis. Ct. App. 1994)* (explaining that statute fails to specify any particular procedure).

n326. Adz. Admin. Code R9-10-214 (West, WESTLAW through Dec. 31, 1999). See also Conn. Agencies Regs. 19-13-D3(b)(c) (West, WESTLAW through June 27, 2000) (establishing that "governing board" will manage hospital, adopt bylaws, annually designate medical staff, select hospital administrator, and create "joint conference committees"); Conn. Agencies Regs. 19-13-D3(c) (West, WESTLAW through Aug. 10, 1999) (outlining structure of medical staff and requiring medical staff bylaws include procedures for administration of privileges awarded to medical staff members); I11. Admin. Code tit. 77, 250.310 (West, Westlaw through Aug. 25, 2000) (mandating medical staff organize according to "bylaws, rules and regulations approved by governing Board"); Kan. Admin. Regs. 28-34-6a(e) (West, WESTLAW through Jan. 1, 1999) (ordering medical staff to adopt bylaws, rules, and regulations to be approved by the governing board, which must delineate "the organizational structure of the medical staff," peer review procedures, and structure and purpose of standing committee). For federal Medicare and Medicaid participants, the requirements are identified in *42 C.F.R. 482.22(c)* (1998).

n327. State hospital licensing requirements are regulatory in nature and typically do not create private causes of action.

n328. See *Janda v. Madera Cmty. Hosp., 16 F. Supp. 2d 1181, 1188 (E.D. Cal. 1998)* (explaining additional duties, beyond those in bylaws, constitute consideration).

n329. See *Gianetti v. Norwalk Hosp., 557 A.2d 1249, 1254 (Conn. 1989)* (looking at physician's relationship with hospital after physician becomes member of staff and concluding contract exists); *Virmani v. Presbyterian Health Servs. Corp., 488 S.E.2d 284, 288 (N.C Ct. App. 1997)* (finding contract by comparing doctor's relationship with hospital before and after joining staff).

n330. See *Gianetti, 557 A.2d at 1254* (stating that after extending privileges, hospital has "done something it was not already bound to do"); *Virmani, 488 S.E.2d at 288* (holding bylaws integral part of contract).

n331. See *Gianetti, 557 A.2d at 1254* (stating that extension of privileges equates to additional consideration); *Virmani, 488 S.E.2d at 288* (finding mutual assent to include bylaws as part of contract).

n332. See *Gianetti, 557 A.2d at 1254* (finding no duty to extend privileges); *Virmani, 488 S.E.2d at 288* (stating offer to practice medicine by hospital exceeds statutory duty).

n333. See *VirmanL 488 S.E.2d at 288* (noting that "the hospital receives the benefit of providing care to the physician's patients").

n334. See *id. at 288* (holding that "valid and enforceable contract existed.., and.., the Bylaws were an integral part of that contract").

n335. See *Gianetti, 557 A.2d at 1254-55* (finding consideration in privilege to practice medicine in hospital). See also *Owens v. New Britain Gen. Hosp., 643 A.2d 233, 239-40 & n.25 (Conn. 1994)* (recognizing Gianetti's holding that extension of medical staff privileges in return for agreement to abide by bylaws constituted valid consideration); *VirmanL 488 S.E.2d at 287-88* (finding contract exists where parties agree to staff privileges). In *Robles v. Humana Hosp. Cartersville, 785 F. Supp. 989 (N.D. Ga. 1992), the* Northern District of Georgia acknowledged but rejected this possible basis for consideration by stating: "This mutually beneficial relationship, however, goes to the arrangement between the two parties, not to whether the bylaws, per se, are a contract as Plaintiff claims. Whether the bylaws per se constitute a contract is a wholly different question." *Robles, 785 F. Supp. at 1001 n.lO.* The rationale behind this statement is obscure. Perhaps, the court merely echoes Gianetti where the court held that bylaws alone did not constitute a contract. See *Gianetti, 557 A.2d at 1254.* But Gianetti, which Robles relied upon, agreed that in the context of the totality of the hospital/physician relationship the bylaws were enforceable as part of the whole contractual relationship, a conclusion Robles does not consider. See *id. at 1255.*

n336. John Hulston, et al., supra note 290.

n337. Id. at 354.

n338. The mutuality of obligation concept requires "that both parties to a contract must be bound or neither is bound." 2 Perillo & Bender, supra note 307, 6.1, at 197; accord, e.g., *Commercial Movie Rental Inc. v. Larry Eagle, Inc., 738 F. Supp. 227, 229-30 (W.D. Mich. 1989)* (explaining need for mutuality of obligation in contracts); *Bernstein, Bernstein, Wile & Gordon v. Ross, 177 N. W.2d 193, 195 (Mich. Ct. App. 1970)* (lack of mutuality invalidates contract).

n339. See e.g., *Commercial Movie Rental, 738 F. Supp. at 230* ("Where contract obligates only one party, while exempting the other party from any obligation to do so, it lacks mutuality and is valid for want of consideration."); *Munoz v. Flower Hosp., 507 N.E.2d 360, 365 (Ohio Ct. App. 1985)* (finding bylaws not contract because "no mutuality of obligation"); *Manczur v. Southside Hosp., 183 N.Y.S. 2d 960, 962 (N. Y. Sup. Ct. 1959)* (finding "no mutuality of obligation or consideration"). See also *Zipper v. Health Midwest, 978 S.W.2d 398, 416 (Mo. Ct. App. 1998)* (noting mutuality of obligation requirement).

n340. *Restatement (Second) of Contracts 79 &* cmt. f (1981); accord *Greene v. Oliver Realty, Inc., 526 A.2d 1192, 1200 (Pa. Super Ct. 1987)* (stating that "mutuality of obligation is a thoroughly discredited notion"); 2 Perillo & Bender, supra note 307, 6. i, at 197 (explaining that "the so-called requirement of mutuality of obligation is now widely discredited"). But see Val D. Ricks, In Defense of Mutuality of Obligation: Why "Both Should Be Bound, or Neither," *78 Neb. L. Rev. 491, 547 (1999)* (defending mutuality of obligation doctrine).

n341. See *Restatement (Second) of Contracts 77* cmt. a (1981). See also id. 2 cmt. e (explaining illusory promises).

n342. See 1 Perillo, supra note 305, 1.17 at 49 (stating performance of illusory promise equates to consideration).

n343.2 Perillo & Bender, supra note 307, 6.2, at 219-20. See also *Weiner v. McGraw-Hill, Inc., 443 N.E.2d441, 444 (N. Y. 1982)* (holding enforceable termination procedures in handbook and mutuality of obligation not required); *Small v. Springs Indus., Inc., 357 S.E.2d 452, 455 (S.C. 1987)* (stating jury could decide whether employer was contractually bound by discharge process in handbook and bulletin even in absence of mutuality).

n344. See *Terre Haute Reg'l Hosp., Inc. v. El-Issa, 470 N.E.2d 1371, 1377 (Ind. Ct. App. 1984)* (stating "the doctrine of mutuality of obligation does not require that every duty within an agreement be based upon a corresponding obligation").

n345. See, e.g., *Webman v. Little Co. of Mary Hosp., 46 Cal. Rptr. 2d 90, 96 (Cal. Ct. App. 1995)* (stating that applicants, by signing application, agree to abide by bylaws); *Gianetti v. Norwalk Hosp., 557A.2d 1249, 1250 (Conn. 1989)* (stating physician agreed in writing to abide by bylaws); *Babcock v. St. Francis Med. Ctr., 543 N. W.2d 749, 760 (Neb. Ct. App. 1996)* (stating bylaws require all applicants agree to be bound by them); *Virmani v. Presbyterian Health Servs. Corp., 488 S.E.2d 284, 288 (N.C. Ct. App. 1997)* (stating that under bylaws provision, physician agreed to be bound by them); *Rees v. Intermountain Health Care, Inc., 808 P.2d 1069, 1076 (Utah 1991)* (finding "hospitals generally will not grant a doctor privileges at the hospital until the doctor agrees to abide by the bylaws of the hospital."); *Bass v. Ambrosius, 520 N. W.2d 625, 628 (Wis. Ct. App. 1994)* (observing that physician must agree to bylaws in signed application). See also Sullivan v Baptist Mem'l Hosp. - *Golden Triangle, Inc., 722 So. 2d 675, 677 (Miss. 1998)* (stating that in reappointment application physicians agreed to be bound by bylaws). JCAH's Guidelines for the Formulation of Medical Staff Bylaws 1971 includes a bylaws provision requiring that "every application for staff appointment shall be signed by the applicant and shall contain the applicant's specific acknowledgment of every medical staff member's obligations.., to abide by the medical staff bylaws, rules and regulations...." JCAH Guidelines for Bylaws, supra note 92, at 8. The guidelines also provided for a provision stating that:

The application form shall include a statement that the applicant has received and read the bylaws of the hospital governing body and the bylaws, rules and regulations of the medical staff and that he agrees to be bound by the terms thereof if he is granted membership and/or clinical privileges and to be bound by the terms thereof without regard to whether or not he is granted membership and/or clinical privileges in all matters relating to consideration of his application.

Id. at 12 (non-departmental hospitals); accord, e.g., HCWP Model Bylaws, supra note 92, at 4.4-9(c)(1); UTMB Bylaws, supra note 92, at 2.3.1. State law may also require medical staff members to agree to be bound by the bylaws. See, e.g., Mo. Stat. Ann. 205.195(1), 206.105(1) (1996) (requiring every physician, podiatrist, and dentist applying for staff membership to "give specifically" his or her "willingness to abide by the bylaws of the board and the staff in all respects.... ").

n346. JCAH Guidelines for Bylaws, supra note 92, at 8.

n347. Id. at 12; accord HCWP Model Bylaws, supra note 92, at 4.4-9(c)(1); UTMB Bylaws, supra note 92, at 2.3.1.

n348. See *Restatement (Second) of Contracts 71* (1981) (discussing requirement of consideration as bargained for performance or return promise).

n349. See JCAH Guidelines for Bylaws, supra note 92, at 11 (discussing importance of immunity from liability).

n350. See id. at 8, 47 (mandating attendance of staff meetings).

n351. See id. at 11 (authorizing background checks).

n352. See id. at 22 (requiring compliance with hearing or review procedures).

n353. See id. at 28 (failing to raise issues at original hearing equates to a wavier).

n354. See JCAH Guidelines for Bylaws, supra note 92, at 11 (explaining applicant's burden).

n355. See id. at 15 (explaining applicant must evidence his qualifications).

n356. Id. at 7.

n357. See, e.g., *Terre Haute Reg'l Hosp., Inc. v. El-Issa, 470 N.E.2d 1371, 1377 (Ind. Ct. App. 1984)* (noting physician's requirement to "participate in the operation of the Medical and Dental Staff" by, inter alia, participating in quality assurance programs).

n358. See also id. (stating bylaws required physician to attend various meetings, serve on committee and in staff positions, participate in quality assurance programs, participate in on-call program); *East Tex. Med. Ctr. Cancer Inst. v. Anderson, 991 S. W.2d 55, 62-63 (Tex. Ct. App. 1998)* (noting physician's consideration and duties under bylaws). For examples of bylaws, see Presbyterian Hosp. Bylaws, supra note 92; Yale-New Haven Hosp. Bylaws, supra note 92; HCWP Model Bylaws, supra note 92; UTMB Bylaws, supra note 92; OHSU Bylaws, supra note 311.

n359. JCAH Guidelines for Bylaws, supra note 92, at 12. See also JCAHO Manual, supra note 1, at MS-32 ("applicant... is informed of existing bylaws, rules and regulations, and policies regarding the application process and agrees, in writing, that he or she will be bound by them").

n360. See supra Part III.B.4.a for additional discussion of the reasoning of courts that have refused to recognize bylaws as contracts.

n361. See *Robles v. Humana Hosp. Cartersville, 785 F. Supp. 989, 1002 (N.D. Ga. 1992)* (reasoning plaintiff had no input into or power to change bylaws); *Gianetti v. Norwalk Hosp., 557 A.2d 1249, 1254 (Conn. 1989)* (finding plaintiff made no claim he had input into bylaws); *Zipper v. Health Midwest, 978 S. W.2d 398, 416 (Mo. Ct. App. 1998)* (stating no bargained for exchange because doctor did not have input or power to change bylaws).

n362. *Restatement (Second) of Contracts 71(1)* (1981).

n363. In the area of insurance for example, insurance policies are considered to be contracts notwithstanding the lack of bargaining power or negotiation over specific terms in the policy. See *Tackett v. State Farm Fire & Cas. Ins. Co., 653 A.2d 254, 264 (Del. 1995)* (agreeing with jurisdictions that insurance disputes are subject to constructual analysis); Collier v. MD - *Individual Practice Ass'n, 607A.2d 537, 539 (Md. 1992)* (stating in Maryland, insurance policies are construed like contracts); *Dairyland Ins. Co. v. Douthat, 449 S.E.2d 799, 801 (Va. 1994)* (observing that insurance policies are contracts to be construed under general contract principles).

n364. *Restatement (Second) of Contracts 71* cmt. b (1981).

n365. See JCAHO Manual, supra note 1, MS.2, at MS.3 ("Each medical staff develops and adopts bylaws and rules and regulations to establish a framework for self-governance of medical staff activities and accountability to the governing body."); MacEachern, supra note 8, at 165 (stating bylaws compiled by committee, then adopted by

whole staff). See also, e.g., *Mo. Ann. Stat. 205.195 (2)*, 206.105 (2) (West 1996) (providing for professional staff to initiate and adopt bylaws and rules); Ariz. Admin. Code R9-10-214 (D) (West, WESTLAW through Aug. 31, 1999) (stating that medical staff shall adopt bylaws); Kan. Admin. Regs. 28-34-6a(b) (West, WESTLAW through Jan. 1, 1999) (same).

n366. For examples of statutes requiring bylaws to be adopting by a governing body, see, Fla. Admin. Code Ann. r. 59A-3.220(1) (West, WESTLAW through Aug. 1, 2000) (stating that medical staff bylaws must be "approved by the governing body"); I11. Admin. Code tit. 77, 250.310(a) (West, WESTLAW through Aug. 25, 2000) (requiring governing body approve medical staff bylaws). See also *42 C.F.R. 482.22(c)(1)* (1999); JCAHO Manual, supra note 1, MS.2.1, at MS-3.

n367. See JCAHO Manual, supra note 1, M.S.2.1, at MS-3 for requirements necessary to adopt bylaws, rules, and regulations.

n368. *245 N.W.2d 472 (S.D. 1976).*

n369. *St. John's, 245 N.W.2d at 473.*

n370. Id.

n371. Id.

n372. Id.

n373. *Id. at473-74.*

n374. *St. John's, 245 N.W.2d at 474.*

n375. *Id. at 475.*

n376. See, e.g., Groseclose, supra note 92, at 27-28 ("The authority to adopt bylaws, like the authority for a corporation to come into existence, is statutory. Typically, that authority is unilaterally vested in the governing board. Hence the terms of the contract will be what one party says they are.").

n377. See *St. Mary's Hosp., Inc. v. Radiology Profl Corp., 421 S.E.2d 731, 736 (Ga. Ct. App. 1992)* (holding "hospitals are entitled to change the staff bylaws").

n378. See *Robles v. Humana Hosp. Cartersville, 785 F. Supp. 989, 1000, 1002 & n.9 (N.D. Ga. 1992)* (calling bylaws "hospital bylaws," but citing cases involving medical staff bylaws).

n379. See *Gianetti v. Norwalk Hosp., 557 A.2d 1249, 1252-53 (Conn. 1989)* (reciting hospital's argument). See also *Janda v. Madera Cmty. Hosp., 16 F. Supp. 2d 1181, 1185 (E.D. Cal. 1998)* (citing Gianetti).

n380. See *Zipper v. Health Midwest, 978 S. W.2d 398, 416-17 (Mo. Ct. App. 1998)* (finding that hospital "had the right to unilaterally change the procedures set forth in the bylaws without consultation with anyone on the medical staff and to impose those bylaws on its medical staff"). The court cited no bylaw provisions supporting this conclusion. Possibly, the court referred to the hospital's own corporate bylaws rather than the medical staff bylaws. However, the court cited and relied on cases involving medical staff bylaws. See *id. at 416* (citing *Gianetti, 557 A.2d at 1256; Balkissoon v. Capitol Hill Hosp., 558 A.2d 304 (D.C. Cir. 1989); Todd v. Physicians & Surgeons Cmty. Hosp., Inc., 302 S.E.2d 378 (Ga. Ct. App. 1983))*. If the court is referring to the medical staff bylaws, its statement is highly suspect in view of Missouri law requiring that "the professional staff of the hospital.., shall initiate and, with the approval of the board, adopt bylaws," *Mo. Ann. Star. 205.195(2),* 206.105(2) (1996),

and JCAHO standards requiring the medical staff itself to adopt both the bylaws and any amendments to them. JCAHO Manual, supra note 1, M.S.2, M.S.2.1, at MS-3.

n381. See *Virmani v. Presbyterian Health Servs. Corp., 488 S.E.2d 284, 288 n.5 (N.C. Ct. App. 1997)* (noting that bylaws were not unilateral because staff was involved in formulating and recommending them).

n382. See 4 Williston & Lord, supra note 307, 8:4, at 41 (stating that under promissory estoppel, courts in effect form contract despite absence of consideration).

n383. See *Simpson Consulting, Inc. v. Barclays Bank PLC., 490 S.E.2d 184, 193 (Ga. Ct. App. 1997)* ("Promissory estoppel may apply to an executory promise without any other consideration, because detrimental reliance supplies consideration as a matter of waiver and estoppel.").

n384. See *D'Ulisse-Cupo v. Bd. of Dirs., 520 A.2d 217, 221 (Conn. 1987)* (recognizing contractual liability where action induced by reliance on promise); *Moukarzel v. Oxygen Elecs., LLC, No. CV990359965S, 1999 WL 643370, at 3* (Conn. Super. Ct. Aug. 12, 1999) (citing D'Ulisse-Cupo and characterizing reliance as consideration "substitute").

n385. See *Restatement (Second) of Contracts 90* at 242 (1981) (listing elements of promissory estoppel); 4 Williston & Lord, supra note 307, 8:5 (discussing elements of promissory estoppel). See also, e.g., *United of Omaha v. Hieber, 698 N.E.2d 869, 876 (Ind. Ct. App. 1998)* (applying five elements of promissory estoppel to facts of case), modified, *701 N.E.2d 622 (Ind. Ct. App. 1998); Ardtv. Titan Ins. Co., 593 N.W.2d 215, 219 (Mich. Ct. App. 1999)(listing* elements of promissory estoppel); *Allied Vista, Inc. v. Holt, 987 S. W.2d 138, 141 (Tex. Ct. App. 1999)* (stating elements of promissory estoppel); *Bouwens v. Centrilift, 974 P.2d 941, 947 (Wyo. 1999)*

(finding no promissory estoppel because first statement of "promise" was missing).

n386. See JCAH, Guidelines for Bylaws, supra note 92, at 21-30 for an outline of hearing and appellate review procedures and JCAHO Manual, supra note 1, MS.2.3.2, at MS-3, MS.5.2, at MS-7 for a discussion of fair hearing and appellate review. For examples of cases discussing these provisions in bylaws, see *Miller v. Nat'l Med. Hosp., Inc., 177 Cal. Rptr. 119, 128-31 (Cal. Ct. App. 1981)* (providing, as attachment, section of bylaws dealing with appellate procedures); *Owens v. New Britain Gen. Hosp., 643 A.2d 233, 235-37, 242 nn.4, 6-7, 9-12, 15, 17 & 29 (Conn. 1994)* (discussing hospital procedures requiring second opinions and psychiatric consultations and bylaws dealing with notice); *Campbell v. St. Mary's Hosp., 252 N. W.2d 581, 588-90 (Minn. 1977)* (listing hearing and review procedures in bylaws); *Munoz v. Flower Hosp., 507 N.E.2d 360, 362 n.1 (Ohio Ct. App. 1985)* (listing appointment procedures); *Brinton v. IHC Hosps., Inc., 973 P.2d 956, 962-63, 968-69, 973 nn.6, 8-9, 18, 20, 28 (Utah 1998)* (discussing probation terms, review procedures and standards).

n387. See supra at notes 344-59 for a discussion of the specific promises in the staff bylaws.

n388. JCAH Guidelines for Bylaw, supra note 92, at 21.

n389. *Bulman v. Safeway, Inc., 978 P.2d 568, 573 (Wash. Ct. App. 1999).*

n390. See supra notes 89-112 and accompanying text for a discussion of the negative effect of the loss of privileges.

n391. See *Holt v. Good Samaritan Hosp. & Health Ctr., 590 N.E.2d 1318, 1322 (Ohio Ct. App. 1990)* (finding record did not indicate intent by either party to be bound by bylaws); *Munoz v. Flower Hosp., 507 N.E.2d 360, 365 (Ohio Ct. App. 1985)* (finding hospital not bound by bylaws and bylaws binding only if intent to be bound). See also *Tredrea v. Anesthesia & Analgesia, P.C., 584 N. W.2d 276, 285 (Iowa 1998)* (focusing on whether bylaws indicate intent to be bound); cf. *Bouquett v. St. Elizabeth Corp., 538 N.E.2d 113, 115 & n.1 (Ohio 1989)* (questioning whether hospital's board or parent corporation is bound by medical staff bylaws).

n392. See supra notes 344-45 and accompanying text for a discussion of requirement that physician agrees to be bound by bylaws.

n393. *704 N.E.2d 698 (Ill. App. Ct. 1998)*, affd in pt., rev'd in pt. on other grounds, *Nos. 86952, 87120, 2000 WL 1599464, at 1* (Ill. Oct. 26, 2000).

n394. *Garibaldi, 704 N.E.2d at 704.*

n395. Id. (quoting *Garibaldi v. Applebaum, 653 N.E.2d 42 (Ill. App. Ct. 1995)).*

n396. Id. at 705.

n397. Id. The Illinois Supreme Court reversed Garibaldi in part but expressly did not decide the question of whether the hospital's bylaws were a contract. *Garibaldi v. Applebaum, Nos. 86952, 87120, 2000 WL 1599464, at 4* (I11. Oct. 26, *2000).*

n398. *Bouquett v. St. Elizabeth Corp., 538 N.E.2d 113, 115 (Ohio 1989);* accord *Terre Haute Reg 'l Hosp., Inc. v. El-Issa, 470 N.E.2d 1371, 1377 (Ind. Ct. App. 1984)* (quoting medical staff bylaws).

n399. *Bass v. Ambrosius, 520 N.W.2d 625, 628 (Wis. Ct. App. 1994).*

n400. JCAHO Manual, supra note 1, at MS-2 to MS-3 (emphasis added).

n401. Id. at MS.2.2, at MS-3.

n402. See *Janda v. Madera Cmty. Hosp., 16 F. Supp. 2d 1181, 1188-89 (E.D. Cal. 1998)* (comparing assurances in bylaws with employer rules and policies and citing employee handbook cases); *Tredrea v. Anesthesia & Analgesia, P.C., 584 N.W.2d 276, 285 (Iowa 1998)* (citing "analogous cases involving employee handbooks" in deciding whether bylaws were a contract); *Bass, 520 N. W.2d at 627* (comparing bylaws with employee handbook); Hulston, et al., supra note 290, at 354.

n403. See infra notes 408-16 and accompanying text for a discussion of courts that have found contract rights in employee manuals.

n404. See 2 Mark A. Rothstein, et al., Employment Law 9.3, at 239 (1994) (noting that some courts held that statements made in employment handbooks did not create contractual obligations because of lack of consideration).

n405. See id. at 526 (concluding that approximately three-quarters of the states hold promises in manuals binding).

n406. See id. (stating "courts have addressed the consideration and mutuality of obligation obstacles either by viewing employment manuals as unilateral contracts or by applying the doctrine of promissory estoppel").

n407. *Duldulao v. St. Mary of Nazareth Hosp. Ctr., 505 N.E.2d 314, 318 (Ill. 1987).*

n408. For example, according to the JCAH Guidelines for Bylaws, supra note 92, the bylaws state that recommendations for reappointment "shall be based upon" a number of listed factors, id. at 14; redetermination of clinical privileges "shall be based upon" a number of listed factors, id. at 15; a physician facing adverse action "shall be entitled to a hearing" and potentially an appellate review, id. at 21; and "all hearings and appellate reviews shall be in accordance with the procedural safeguards set forth in this Article VIII to assure that the affected practitioner is accorded all rights to which he is entitled," id. at 21.

n409. See JCAHO Manual, supra note 1, MS.5.1.1, at MS-7 (stating that applicant "is oriented" to bylaws and agrees to be bound by them); id. MS.2.4.2, at MS-4 (requiring that if significant changes are made to bylaws, individuals are provided with revised text); id. at MS-32 (stating that applicant for appointment or reappointment "is informed of existing bylaws"). See also, *Kiester v. Humana Hosp. Alaska, Inc., 843 P.2d 1219, 1221 (Alaska 1992)* (noting physician received bylaws as part of application); *Virmani v. Presbyterian Health Servs. Corp., 488 S.E.2d 284, 286 (N. C. Ct. App. 1997)* (noting plaintiff received copy of bylaws upon his application for privileges).

n410. See supra notes 344-45 and accompanying text for a discussion of the requirement that physician agree to be bound by bylaws.

n411. *685 P.2d 1081 (Wash. 1984).*

n412. *Thompson, 685 P.2d at 1088.*

n413. Some courts have found enforcement of bylaws more compelling than enforcement of employee handbooks. *See Garibaldi v. Applebaum, 704 N.E.2d 698, 704-05 (Ill. App. Ct. 1998)* (holding disclaimers effective in handbook but not effective in bylaws), affd in pt., rev'd in

pt. on other grounds, *Nos. 86952, 87120, 2000 WL 1599464* (I11. Oct. 26, 2000); *Virmani, 488 S.E.2d at 288 n.5* (stating that bylaws do not share handbook's unilateral nature).

n414. See *Gonzalez v. San Jacinto Methodist Hosp., 880 S. W.2d 436, 438-39 (Tex. Ct. App. 1994)(distinguishing* hospital bylaws from medical staff bylaws and finding procedural rights under hospital bylaws contractual). See also *Natale v. Sisters of Mercy, 52 N. W.2d 701, 709 (Iowa 1952)* (holding governing board not bound by provisions of medical staff bylaws); *Weary v. Baylor Univ. Hosp., 360 S. W.2d 895, 897 (Tex. Civ. App. 1962)* (stating that medical staff bylaws did not limit power of board); cf. *Tredrea v. Anesthesia & Analgesia, P.C., 584 N. W.2d 276, 284-87 (Iowa 1998)* (distinguishing hospital's bylaws from medical staff bylaws); *Ishak v. Fallston Gen. Hosp. & Nursing Ctr., 438 A.2d 1369, 1372 (Md. Ct. Spec. App. 1982)* (noting argument that only hospital bylaws are relevant, not medical staff bylaws). But see *Lewisburg Cmty. Hosp., Inc. v. Alfredson, 805 S. W.2d 756, 759 (Tenn. 1991)* (rejecting the distinction between hospital and medical staff bylaws).

n415. See *Hongsathavij v. Queen of Angels~Hollywood Presbyterian Med. Ctr., 73 CaL Rptr. 2d 695, 699 n.2 (Cal. Ct. App. 1998)* (noting hospital's medical staff is separate legal entity, an unincorporated association); *Corleto v. Shore Mem'l Hosp., 350 A.2d 534, 539 (N.J. Super. Ct. 1975)* (concluding medical staff is unincorporated association capable of being sued); *Manczur v. Southside Hosp., 183 N.Y.S. 2d 960, 961-62 (N. Y. Sup. Ct. 1959)* (holding medical staff is unincorporated association); *St. John's Hosp. Med. Staff v. St. John Reg'l Med. Ctr., 245 N. W.2d 472, 474 (S.D. 1976)* (finding medical staff is unincorporated association with standing to bring declaratory judgment action). See also Isele, supra note 68 (medical staff is separate legal entity, usually an unincorporated association).

n416. See *Manczur, 183 N. Y.S. 2d at 961-62* (finding medical staff bylaws not binding on hospital board).

n417. See JCAHO Manual, supra note 1, GO.2.2.1, at GO-4 ("The medical staff has the right to representation (through attendance an voice) by one or more medical staff members selected by the medical staff, at governing body meeting."). See also supra notes 27-31,236-41 and accompanying text for an analysis of legal requirements mandating creation of an organized medical staff.

n418. See also supra notes 27-31 and accompanying text for an analysis of legal requirements mandating creation of an organized medical staff.

n419. See JCAHO Manual, supra note 1, MS. 1, at MS-2 (medical staff accountable to hospital's governing body for quality of services provided by those with clinical privileges); MacEachern, supra note 8, at 143.

n420. According to one authority: "Although few governing bodies use this power to impose bylaws on medical staffs, the hospital administration nevertheless tends to have significant power to influence the form of the bylaws that will be adopted by the medical staff." Glen A. Reed & Robert W. Miller, The Hospital Medical Staff: Due Care with Due Process, in Representing Health Care Facilities 25, 37 (Matthew M. Strickler & Frederic L. Ballard, Jr. eds., 1981). Some courts hold that upon approval or ratification by the hospital board the medical staff bylaws become binding upon the hospital. See *Hager v. Venice Hosp., Inc., 944 F. Supp. 1530, 1534 (M.D. Fla. 1996)* (stating hospital bylaws, when approved and adopted by governing board, became binding and enforceable contract between hospital and physicians comprising medical staff), affd, *132 F.3d 1461 (11th Cir. 1997); Lawler v. Eugene Wuesthoff Mem'l Hosp. Ass'n, 497 So. 2d 1261, 1264 (Fla. Dist. Ct. App. 1986)* (same);

Joseph v. Passaic Hosp. Ass'n, 141 A.2d 18, 23 (N.J. 1958) (same). In *Islami v. Covenant Med. Ctr., Inc., 822 F. Supp. 1361 (N.D. Iowa 1992), the* hospital argued that although the hospital's board of directors might be bound under the bylaws, the hospital was not. *Id. at 1371.* The court rejected that argument, finding no distinction between the hospital and its board, *Id. at 1371.* Cf. *Munoz v. Flower Hosp., 507 N.E.2d 360, 364 n.2 (Ohio Ct. App. 1985)* (concluding hospital acts through and is represented by its board).

n421. See 1 Glen A. Reed, et al., Treatise on Health Care Law 1.0315] (Michael G. MacDonald, et al., eds., 1999).

n422. JCAHO Manual, supra note 1, MS-3 (emphasis added).

n423. See *Gonzalez v. San Jacinto Methodist Hosp., 880 S. W.2d 436, 438-39 & nn.2-3 (Tex. Ct. App. 1994)* (stating hospital bylaws set forth specific rights and duties for each physician). See also JCAHO Manual, supra note 1, M.S.2.4.1, at MS-4 (stating medical staff bylaws and governing body's bylaws must not conflict). Some courts hold that upon approval or ratification by the hospital board the medical staff bylaws become binding upon the hospital. See, e.g., *Joseph v. Passaic Hosp. Ass'n, 141 A.2d 18, 23 (N.J. 1958)* (noting that, upon ratification by board of governors of hospital, bylaws "became a constituent part of the Association's elemental law").

n424. In a closely related context, the courts are split on the question of whether a hospital can conspire with its medical staff under federal antitrust laws. Some hold that the medical staff in conducting peer review acts as the hospital's agent and therefore cannot conspire with the hospital. See, e.g., *Okusami v. Psychiatric Inst., 959 F.2d 1062, 1065 (D.C. Cir. 1992)* (finding no basis for proposition that hospital and its medical staff have divergent interests); *Oksanen v. Page Mem'l Hosp., 945 F.2d 696, 705 (4th Cir. 1991)*

(en banc) (stating that hospital and its staff should not be seen as possible co-conspirators); *Nurse Midwifery Assocs. v. Hibbett, 918 F.2d 605, 613 (6th Cir. 1990)* (finding that, in general, the intracorporate conspiracy doctrine prevents a finding of conspiracy between a hospital and its medical staff), modified on rehearing, *927 F.2d 904 (6th Cir. 1991); Nanavati v. Burdette Tomlin Mem'l Hosp., 857 F.2d 96, 118 (3d Cir. 1988)* (concluding hospital could not conspire with executive committee). Under this view, the medical staff is "a natural component of the hospital's management structure." *Oksanen, 945 F.2d at 703.* Other courts, however, hold that the hospital and medical staff are separate entities capable of conspiracy. See *Bolt v. Halifax Hosp. Med. Ctr., 891 F.2d 810, 819 (11th Cir. 1990)* (finding hospital and its medical staff unanalogous to corporate structure and therefore capable of conspiracy with each other); *Oltz v. St. Peter's Cmty. Hosp., 861 F.2d 1440, 1450 (9th Cir. 1988)* (finding interests between hospital and its anesthesiologists "not as wed" as ties between corporation and its officers or employees).

n425. See, e.g., *Janda v. Madera Crnty. Hosp., 16 F. Supp. 2d 1181, 1184 (E.D. Cal. 1998)* (referring to medical staff bylaws as "hospital bylaws"); *Babcock v. St. Francis Med. Ctr., 543 N. W.2d 749, 759-60 (Neb. Ct. App. 1996)* (noting physicians applying for staff privileges must agree to be bound by "hospital bylaws"); *Lewisburg Cmty. Hosp., Inc. v. Alfredson, 805 S. W.2d 756, 759 (Tenn. 1991)* (referring to bylaws collectively as "hospital and staff bylaws"); *Bass v. Ambrosius, 520 N. W.2d 625, 627-28 & nn.6-7 (Wis. Ct. App. 994)* (making no distinction between hospital and medical staff bylaws).

n426. This in no way implies that all the procedures and provisions of the bylaws will apply to applicants. By their terms, most of the provisions will apply only to staff members and not to applicants.

n427. See supra notes 288-413 and accompanying text for an analysis of the contract issue.

n428. Id.

n429. Id.

n430. See *Robles v. Humana Hosp. Cartersville, 785 F. Supp. 989, 1002 (N.D. Ga. 1992)* (stating while bylaws do not constitute contracts, courts can enjoin hospitals to follow bylaws). See also Hulston, et al., supra note 290, at 355 (arguing bylaws should not be considered contract giving rise to cause of action for damages but should be enforceable in action for injunctive relief); cf. *Zipper v. Health Midwest, 978 S.W.2d 398, 417 (Mo. Ct. App. 1998)* (finding failure to state cause of action "because Dr. Zipper sought only contractual damages for MCI's alleged breach of [hospital] bylaws and contractual damages are not an available remedy for breach of [hospital] bylaws"). But see *Manczur v. Southside Hosp., 183 N. Y.S. 2d 960, 962 (N. Y. Sup. Ct. 1959)* (refusing to grant damages); *Weary v. Baylor Univ. Hosp., 360 S.W.2d 895, 896-97 (Tex. Civ. App. 1962)* (refusing injunction and damages).

n431. *785 F. Supp. 989 (N.D. Ga. 1992).*

n432. See *Robles, 785 F. Supp. at 1002* (reasoning that breach of contract action would run counter to policy of allowing hospitals to grant or withhold staff privileges).

n433. See id. (reasoning that state legislature required bylaws intending that hospitals would follow bylaws). See also *Owens v. New Britain Gen. Hosp., 643 A.2d 233, 240 (Conn. 1994)* (stating judicial review for enforcement of bylaws may be based on legal duty imposed by state law); *St. Mary's Hosp., Inc. v. Radiology Profll Corp., 421 S.E.2d 731, 736 (Ga. Ct. App. 1992)* (holding staff bylaws alone confer no contractual rights but are enforceable in tort).

n434. See *42 U.S.C. lllll(a)* (1995) (limiting damages for professional review actions to knowing transmission of false information).

n435. See, e.g., *Ariz. Rev. Stat. 36-445.02(B)* (1993) (limiting relief to injunctions for erroneous decisions); *210 Ill. Comp. Star. Ann. 85/10.2* (Michie 1999) (granting immunity to hospital and peer review members); *Tenn. Code Ann. 63-6-219* (West Supp. 2000) (providing immunity to medical review committees); *Samaritan Health Sys. v. Superior Court, 981 P.2d 584, 589-90 (Ariz. Ct. App. 1998)* (finding hospital immune from damages for breach of contract claim based on failure to follow bylaws under Arizona statute); *Tabora v. Gottlieb Metn'l Hosp., 664 N.E.2d 267, 272 (Ill. App. Ct. 1996)* (stating that under statute hospital cannot be liable for monetary damages to physician as result of peer review); *Gureasko v. Bethesda Hosp., 689 N.E.2d 76, 80 (Ohio Ct. App. 1996)* (citing Ohio statute granting hospitals immunity from damages for their peer review actions); *Eyring v. Fort Sanders Parkwest Med. Ctr., Inc., 991 S.W.2d 230, 234-36, 239 (Tenn. 1999)* (analyzing Tennessee Peer Review Law of 1967 and finding hospital immune from breach of contract damage claim).

n436. See *Everett v. St. Ansgar Hosp., 974 F.2d 77, 80 (8th Cir. 1992)* (citing hospital's bylaws immunity clause). See also *Brader v. Allegheny Gen. Hosp., 167 F.3d 832, 834 (3d*

Cir. 1999) (affirming dismissal based on HCQIA immunity without reaching bylaws' immunity; district court held that hospital was immune under bylaws).

n437. 42 *U.S.C. 11111,* 11151(11) (1995). See also, *Brader, 167 F.3d at 834* (noting application of HCQIA depends upon hospital meeting Act's requirements); *Wayne v. Genesis Med. Ctr., 140 F.3d 1145, 1148 (8th Cir. 1998)* (rejecting cause of action where plaintiff failed to rebut presumption of hospital's compliance with HCQIA's immunity provision).

n438. See, e.g., *Brader, 167 F.3d at 839, 843* (granting summary judgment dismissing bylaws claims based upon HCQIA); *Wayne, 140 F.3d at 1147-49* (holding HCQCIA immunity barred contract claim based upon bylaws).

n439. See infra notes 496-503 and accompanying text for a discussion of immunity statutes and the good faith requirement.

n440. For a critical and cryptic view, see Groseclose, supra note 90, at 28 ("The so-called contract can actually be a vehicle for oppression rather than a meaningful judicial remedy.").

n441. 973 *P.2d 956 (Utah 1998).*

n442. *Brinton, 973 P.2d at 965.*

n443. Id. See also *Bryant v. Glen Oaks Med. Ctr., 650 N.E.2d 622, 631 (Ill. App. Ct. 1995)* (stating that any right to hearing was waived for failure to request hearing within 15 days of notice as required by bylaws); *Renforth v. Fayette Mem'l Hosp. Ass'n, 383 N.E.2d 368, 377 (Ind. Ct. App. 1978)* (holding failure to request hearing deemed waiver under bylaws); *Corines v. Catholic Med. Ctr., Inc., 540 N. Y.S.2d 273, 273-74 (N. Y. App. Div. 1989)* (finding that, under bylaws,

failure to appear at hearing without good cause was waiver of right to hearing or any further review); *East Texas Med. Ctr. Cancer Inst. v. Anderson, 991 S.W.2d 55, 64 (Tex. Ct. App. 1998)* (stating failure to request hearing within ten days was waiver).

n444. *Brinton, 973 P.2d at 966.*

n445.974 *F.2d 77 (8th Cir. 1992).*

n446. *Everett, 974 F2d at 80.*

n447. Id. (alterations in original) (quoting St. John's Bylaws, Art. 14). But see *Westlake Cmty. Hosp. v. Superior Court, 551 P.2d 410, 418-19 (Cal. 1976)* (holding bylaws' exculpatory clause unenforceable as against public policy).

n448. 192 *A.2d 817 (N.J. 1963).*

n449. *Greisman, 192 A.2d at 818.*

n450. *Id. at 819.*

n451. *Id. at 820.*

n452. *Id. at 821* (citations omitted).

n453. Id. (internal citation omitted).

n454. *Greisman, 192 A.2d at 821.*

n455. *Id. at 821-22.*

n456. *Id. at 822-23* (citing *Falcone v. Middlesex County Med. Soc'y, 170 A.2d 791 (N.J. 1961)).*

n457. *Id. at 825.*

n458. Id.

n459. *Sussman v. Overlook Hosp. Ass'n, 222 A.2d 530, 537-38 (N.J. Super. Ct. 1966),* aft'd, *231 A.2d 389 (N.J. Super. Ct. App. Div. 1967).* See also *Balkissoon v. Capitol Hill Hosp., 558 A.2d 304, 308 (D.C. Cir. 1989)* (requiring compliance with bylaws reduces risk of arbitrary decisions but "hospital cannot technically comply with [bylaws] while defeating the purpose inherent in the process they create").

n460. *Greisman v. Newcomb Hosp., 192 A.2d 817, 824 (N.J. 1963)* (stating "our proper concern here is whether the hospital had the right to exclude consideration of the plaintiff, solely because he was a doctor of osteopathy").

n461. See, e.g., *Sokol v. Akron Gen. Med. Ctr., 173 F.3d 1026, 1030 (6th Cir. 1999)* (applying Ohio law and stating "hospitals must provide "procedural due process.., in adopting and applying reasonable, non-discriminatory criteria for the privilege of practicing'"); *Bricker v. Sceva Speare Mem'l Hosp., 281 A.2d 589, 592 (N.H. 1971)* (recognizing rules will be reviewed by court and "set aside if arbitrary, capricious or unreasonable") (citations omitted); *Bouquett v. St. Elizabeth Corp., 538 N.E.2d 113, 114 (Ohio 1989)* (finding decisions of hospital will be set aside if "arbitrary, capricious or unreasonable"); *Nashville Mem'l Hosp., Inc. v. Binkley, 534 S. W.2d 318, 320 (Tenn. 1976)* (stating "duly licensed physician.., cannot be deprived of [the right to practice] by rules, regulations, or actions of the hospital's governing authority that are unreasonable, capricious or discriminatory").

n462. *Silver v. Castle Mem'l Hosp., 497 P.2d 564, 568 (Haw. 1972).*

n463. See *Storrs v. Lutheran Hosps. & Homes Soc'y, Inc., 609 P.2d 24, 28 (Alaska 1980)* (citing Greisman for proposition that hospital "cannot violate due process

standards in denying staff privileges"); *Peterson v. Tuscon Gen. Hosp., Inc., 559 P.2d 186, 189-91 (Ariz. Ct. App. 1976)* (providing lengthy explanation of Greisman holding and its progeny); *Ascherman v. San Francisco Med. Soc'y, 114 Cal. Rptr. 681, 693-97 (Cal. Ct. App. 1974)* (citing Greisman and reviewing holding in detail); *Hawkins v. Kinsie, 540 P.2d 345, 348-49 (Colo. Ct. App. 1975)* (citing Greisman and finding minority of jurisdictions have "concluded that courts should grant relief where the action of the private hospital has been demonstrated to be unreasonable, arbitrary, and capricious"); *Silver v. Castle Mem'l Hosp., 497 P.2d 564, 568 n.5 (Haw. 1972)* (citing Greisman and noting New Jersey as one jurisdiction that held admissions decisions are subject to judicial review); *Bricker v. Sceva Speare Mem'l Hosp., 281 A.2d 589, 592 (N.H. 1971)* (reviewing hospital's decision for due process and reasonable judgment made in good faith); *Berman v. Valley Hosp., 510 A.2d 673, 676 (N.J. 1986)* (citing Greisman and stating that court's review should determine if hospital's decision advances public health care interest); *Kelly v. St. Vincent Hosp., 692 P.2d 1350, 1352 (N.M. Ct. App. 1984)* (citing Greisman and explaining that powers "used in the selection of medical staff" are "fiduciary powers to be exercised reasonably and for the public good"); *Davidson v. Youngstown Hosp. Ass'n, 250 N.E.2d 892, 895 (Ohio Ct. App. 1969)* (agreeing with Greisman reasoning and noting private hospital not immune from public supervision because of its private nature); *Woodard v. Porter Hosp., Inc., 217 A.2d 37, 40 (Vt. 1966)* (citing Greisman and holding courts will intervene when hospital's decision is "unreasonable, arbitrary, capricious or discriminatory"); cf. *Owens v. New Britain Gen. Hosp., 643 A.2d 233, 240 (Conn. 1994)* (citing Greisman and agreeing that hospital's powers held in trust); *Balkissoon v. Capital Hill Hosp., 558 A.2d 304, 308 (D. C. Cir. 1989)* (noting public's substantial interest and holding duty to comply with bylaws independent of contractual right); *Nashville Mem'l Hosp., Inc. v. Binkley, 534 S. W.2d 318, 320 (Tenn. 1976)* (citing Greisman).

States, however, have not uniformly embraced Greisman. See *Barrows v. Northwestern Mem'l Hosp., 525 N.E.2d 50, 52-55 (Ill. 1988)* (expressly rejecting Greisman as representing view of "tiny minority" of states and inconsistent with Illinois public policy); *Bello v. South Shore Hosp., 429 N.E.2d 1011, 1015 (Mass. 1981)* (rejecting Greisman); *Hottentot v. Mid-Maine Med. Ctr., 549 A.2d 365, 369-70 (Me. 1988)* (Hornby, J., concurring) (rejecting Greisman's common law cause of action); cf. *id. at 368-69* (discussing holding in Greisman but declining to adopt or reject it on facts of case).

n464. See, e.g., *Sokol, 173 F.3d at 1029* (concerning limitation of privileges); *Hawkins, 540 P.2d at 346* (involving termination of privileges); *Silver, 497 P.2d at 566* (involving failure to renew temporary privileges); *Bricker, 281 A.2d at 591* (concerning denial of reappointment).

n465. *Greisman, 192 A.2d at 824, 825.*

n466. *Silver, 497 P.2d at 570.*

n467. *Restatement (Second) of Torts 874* cmt. a. (1979); accord *Restatement (Second) of Trusts* 2 cmt. b (1959) (discussing circumstances constituting fiduciary relationship).

n468. Scott FitzGibbon, Fiduciary Relationships are Not Contracts, *82 Marq. L. Rev. 303, 306-07* (1998-99) (footnotes omitted).

n469. See Black's Law Dictionary 625 (6th ed. 1990) (defining fiduciary as: "A person having duty, created by his undertaking, to act primarily for another's benefit in matters connected with such undertaking").

n470. See *Restatement (Second) of Torts 874* cmt. a. (1979) (finding fiduciary relationship imposes duty to act for benefit of another); accord *Restatement (Second) of Trusts* 2 cmt. b (1959) (stating "a person in a fiduciary relationship to another is under a duty to act for the benefit of the other").

n471. The fact that states have their own professional licensing requirements for physicians suggests that the public is acting independently to protect its own interests.

n472. A grocery store provides a vital service to the public but does not thereby become a fiduciary.

n473. Arguably, denial of the services of a qualified physician or denial of the opportunity to select a particular physician is some harm.

n474. Cf. *Restatement (Second) of Torts 874 &* cmt. b (finding fiduciary may be liable to beneficiary for breach).

n475. The California Court of Appeals in *Ascherman v. San Francisco Medical Society, 114 Cal. Rptr. 681, 693-97 (Cal. Ct. App. 1974),* quoted extensively from Greisman in holding a private hospital must grant a physician minimum due process when considering staff privileges. See *id. at 693-97* (quoting Greisman). See also *Blank v. Palo Alto-Stanford Hosp. Ctr., 44 Cal. Rptr. 572, 576 n.2 (Cal. Ct. App. 1965)* (citing Greisman). Greisman itself cited *Willis v. Santa Ana Community Hospital Ass'n, 376 P.2d 568 (Cal. 1962),* to suggest that private hospitals' decisions might not always be discretionary. See *Greisman v. Newcomb Hosp., 192 A.2d 817, 821 (N.J. 1963)* (citing Willis). Similarly, two California Supreme Court decisions involving membership in an orthodontists' society relied upon *Falcone v. Middlesex County Medical Society, 170 A.2d 791 (N.J. 1961),* a forerunner cited in Greisman, in finding review of membership decisions of private associations under a common law fair

procedure theory. See *Pinsker v. Pacific Coast Soc'y, 526 P.2d 253, 260 (Cal. 1974)* (citing Falcone); *Pinsker v. Pacific Coast Soc'y, 460 P.2d 495, 498 (Cal. 1969)* (citing Falcone). The second Pinsker opinion also relied on Sussman and Silver, and cited favorably Ascherman. See *Pinsker, 526 P.2d at 260 n.8, 263* (citing Sussman, Silver, and Ascherman). Again in *Antonv. San Antonio Community Hospital, 567 P.2d 1162 (Cal. 1977)* [Anton II], the California Supreme Court cited Ascherman and Silver to apply the common law fairness doctrine to decisions of private hospitals. See *id. at 1168 n.12* (citing Ascherman and Silver). For a good discussion of the development of California law, see Neil McNiece, Comment, The State of California Law in Hospital Peer Review Cases, *13 Sw. U. L. Rev. 337 (1982)*. See also *Oskooi v. Fountain Valley Reg'l Hosp. & Med. Ctr., 49 Cal. Rptr. 2d 769, 776-77 (Cal. Ct. App. 1996)* (Sills, P.J., concurring) (discussing development of California law).

n476. See e.g., *Miller v. Eisenhower Med. Ctr., 614 P.2d 258, 265, 269-70 (Cal. 1980)* (Mosk, J., dissenting) (allowing review of hospital credentialing procedures); *Antonv. San Antonio Cmty. Hosp., 567 P.2d 1162, 1168 (Cal. 1977)* [Anton II] (reviewing decision and requiring hearing, evidence, and discretion in determination of facts for fair procedure); *Pinsker, 526 P.2d at 263* (recognizing applicant's "judicially enforceable right" to have application considered according to fundamentals of due process); *Goodstein v. Cedars-Sinai Med. Ctr., 78 Cal. Rptr. 2d 577, 583 (Cal. Ct. App. 1998)* (stating "policy of nondisclosure comports with the concept of fair procedure"); *Gaenslen v. Bd. of Dirs., 232 Cal. Rptr. 239, 241-42 (Cal. Ct. App. 1985)* (reviewing hospital's decision under "fair procedure" concept); *Cipriotti v. Bd. of Dirs., 196 Cal. Rptr. 367, 373 (Cal. Ct. App. 1983)* (permitting review of hospital decision under "fair procedure" standard); *Antonv. San Antonio Cmty. Hosp., 183 Cal. Rptr. 423, 431-32 (Cal. Ct. App. 1982)* [Anton I] (noting hospital decision, as one of private agency, reviewable under "fair procedure" standard); *Ascherman v. St. Francis Mem'l Hosp., 119 Cal.*

Rptr. 507, 509 & n.4 (Cal. Ct. App. 1975) (reviewing hospital decision under "fair procedure" standard rather than "due process" standard); *Ascherman, 114 Cal. Rptr. at 693-97* (allowing review of hospital decision).

n477. *567 F.2d 1162 (Cal. 1977)* [Anton II].

n478. *Anton II, 567 P.2d at 1168.*

n479. See, e.g., *Gaenslen, 232 Cal. Rptr. at 241-42* (discussing distinction between due process and fair procedures); *Anton I, 183 Cal. Rptr. at 432 & n.4* (noting proper term for review is "fair procedure" because decision based on common law and not constitutional privileges). The distinction is one of origin and does not indicate the extent of protection provided. See *Goodstein, 78 Cal. Rptr. 2d at 583* (identifying "fairness" as essence of both rights); *Anton I, 183 Cal. Rptr. at 433* (finding "little distinction"); *Applebaum v. Bd. of Dirs., 163 Cal. Rptr. 831, 836 (Cal. Ct. App. 1980)* (identifying "fairness" as "essence of both rights").

n480. *Miller v. Nat'l Med. Hosp., Inc., 177 Cal. Rptr. 119, 124 (Cal. Ct. App. 1981).*

n481. *Miller v Eisenhower Med. Ctr., 614 P.2d 258, 265 (Cal. 1980)* (Mosk, J., dissenting); accord, e.g., *Goodstein, 78 Cal. Rptr. 2d at 582* (discussing whether hospital policy is ""substantially irrational, unlawful or contrary to established public policy or procedurally unfair"") (citation omitted).

n482. See *Miller, 614 P.2d at 271-72* (Mosk, J., dissenting) (discussing standards); *Anton II, 567 P.2d at 1168 & n.12* (discussing similarities in standards).

n483.*567 P.2d 1162 (Cal. 1977).*

n484. *Anton II, 567 P.2d at 1172.*

n485. *Cal. Civ. Pro. Code 1084-1097* (West 1990 & Supp. 2000).

n486. See *Cal. Civ. Pro. Code 1094.5(d)* (West Supp. 2000) (adopting "substantial evidence" standard). See also *Anton I, 183 Cal. Rptr. at 426-27* (citing Section 1094.5(d)).

n487. See *Westlake Cmty. Hosp. v. Superior Court, 551 P.2d 410, 411 (Cal. 1976)* (discussing mandamus requirement and finding successful mandamus action generally required before tort action for damages); *Bollengier v. Doctors Med. Cir., 272 Cal. Rptr. 273, 276-82 (Cal. Ct. App. 1990)* (noting that successful mandamus action required before damage suit can be brought); *Mir v. Little Co. of Mary Hosp., 844 F.2d 646, 650-51 (9th Cir. 1988)* (citing Westlake).

n488. *Hongsathavij v. Queen of Angels~Hollywood Presbyterian Med. Ctr., 73 Cal. Rptr. 2d 695, 703 (Cal. Ct. App. 1998)* (quoting in part *Bonner v. Sisters of Providence Corp., 239 Cal. Rptr. 530, 535 (Cal. Ct. App. 1987));* accord *Oskooi v. Fountain Valley Reg 'l Hosp. &Med. Ctr., 49 Cal. Rptr. 2d 769, 773 (Cal. Ct. App. 1996)(discussing* substantial evidence standard); *Webman v. Little Co. of Mary Hosp., 46 Cal. Rptr. 2d 90, 97-98 (Cal. Ct. App. 1995)* (applying "substantial evidence in the light of the whole record" standard).

n489. See *Rosenblit v. Superior Court, 282 Cal. Rptr. 819, 823 (Cal. Ct. App. 1991)* (discussing independent review).

n490. In its current codification, section 1094.5(d) states:

(d) Notwithstanding subdivision (c), in cases arising from private hospital boards or boards of directors of districts organized pursuant to The Local Hospital District Law, Division 23 (commencing with Section 32000) of the

Health and Safety Code or governing bodies of municipal hospitals formed pursuant to Article 7 (commencing with Section 37600) or Article 8 (commencing with Section 37650) of Chapter 5 of Division 3 of Title 4 of the Government Code, abuse of discretion is established if the court determines that the findings are not supported by substantial evidence in the light of the whole record. However, in all cases in which the petition alleges discriminatory actions prohibited by Section 1316 of the Health and Safety Code, and the plaintiff makes a preliminary showing of substantial evidence in support of that allegation, the court shall exercise its independent judgment on the evidence and abuse of discretion shall be established if the court determines that the findings are not supported by the weight of the evidence.

Cal. Civ. Pro. Code 1094.5(d) (West Supp. 1999).

n491. See *Westlake Cmty. Hosp. v. Superior Court, 551 P.2d 410, 411 (Cal. 1976)* (discussing exhaustion requirement). See also *Mir v. Little Co. of Mary Hosp., 844 F.2d 646, 650-51 (9th Cir. 1988)* (citing Westlake in its discussion of exhaustion requirement); *Bollengier v. Doctors Med. Ctr., 272 Cal. Rptr. 273, 276-82 (Cal. Ct. App. 1990)* (noting successful mandamus action and exhaustion of hospital's administrative process required before damage suit can be brought).

n492. *Mahmoodian v. United Hosp. Ctr., Inc., 404 S.E.2d 750, 755 (W. Va. 1991)* (emphasis added); accord *Babcock v. St. Francis Med. Ctr., 543 N. W.2d 749, 759 (Neb. Ct. App. 1996)* (quoting Mahmoodian); *Brinton v. IHC Hosps., Inc., 973 P.2d 956, 964 (Utah 1998)* (quoting Mahmoodian).

n493. See, e.g., *Mahmoodian, 404 S.E.2d at 755* (court will review to ensure bylaws afford notice and fair hearing procedures).

n494. *Id. at 756.*

n495. *Adkins v, Sarah Bush Lincoln Health Ctr., 544 N.E.2d 733, 741 (Ill. 1989).*

n496. For examples of immunity statutes, *see Ariz. Rev. Stat. Ann. 36-445.02* (West 1993); *Colo. Rev. Stat. 12-36.5-105,* 12-36.5-203 (1999); *210111. Comp. Stat. Ann. 85/10.2* (West 1993); *Ind. Code Ann. 16-21-2-6(b)* (West 1997); *Ky. Rev. Stat. Ann. 311.377* (West 1997); *Mass. Gen. Laws Ann. ch. 111, 203(c)* (West Supp. 2000); and *Tenn. Code Ann. 63-6-219* (Michie 1999). For the federal immunity statute, see *42 U.S.C. 11111(a)* (1995).

n497. *Fla. Stat. Ann. 395.0193 (5)* (West Supp. 2000).

n498. See, e.g., *Ala. Code 6-5-333(a)* (Michie 1993) (applicable only to "dentists, chiropractors, or physicians"); *Cal. Civ. Code 43. 7(e)* (Deering Supp. 1999) (exempting hospitals); *Pa. Stat. Ann. tit. 63, 425.3(b)* (West 1996) (immunizing individuals only); *Axline v. St. John's Hosp. & Health Ctr., 74 Cal. Rptr. 2d385, 388 (Cal. Ct. App. 1998)* (stating California statute applicable to individuals - not hospitals); *Cooper v. Delaware Valley Med. Ctr., 654 A.2d 547, 552-53 (Pa. 1995)* (stating that although Pennsylvania statute subsection (a) applies to hospitals providing information, subsection (b) protects only individuals). But cf. *Eyring v. Fort Sanders Parkwest Med. Ctr., Inc., 991 S. W.2d 230, 234-36 (Tenn. 1999)* (finding ambiguous language of Peer Review Law granted immunity to hospitals).

n499. See *Ariz. Rev. Star. Ann. 36-445.02(B)* (West 1993) ("No hospital.., may be liable in damages to any person who is denied the privilege to practice in a hospital or center or whose privileges are suspended, limited or revoked.").

n500. See, e.g., *Colo. Rev. Stat. 12-36.5-105(2)* (1999) (immunizing hospitals where action in good faith); *Mass. Gen. Laws Ann. ch. 111, 203(c)* (West Supp. 2000) (same); *Wash. Rev. Code Ann. 4.24.250* (West 1988) (same).

n501. See, e.g., *Ga. Code Ann. 31-7-131(2)(K)*, 31-7-132(a) (West 1996) (adopting "without malice" standard). Other states that have adopted the "without malice" standard include Louisiana (La. *Rev. Star. Ann. 13:3715.3(C)* (West Supp. 2000)), Mississippi *(Miss. Code Ann. 73-25-93(2)* (West 1999)), and North Dakota *(N.D. Cent. Code 23-34-06(2)* (Supp. 1999)).

n502. *See D.C. Code Ann. 32-503* (Michie 1998) (adopting "reasonable belief" standard); *Fla. Stat. Ann. 395.0193 (5)* (West Supp. 2000) (adopting "without intentional fraud" standard); *Ind. Code Ann. 16-21-2-6 (b)* (West 1997) (adopting hybrid "in good faith and without malice" standard); *Utah Code Ann. 58-13-4 (2)(Michie* 1998) (adopting "in good faith and without malice" standard).

n503. See, e.g., *Samaritan Health Sys. v. Superior Court, 981 P.2d 584, 589 (Ariz. Ct. App. 1998)* (holding immunity statute barred breach of contract claim); *Noble v. Martin Mem'l Hosp. Ass'n, 710 So. 2d 567, 568-69 (Fla. Dist. Ct. App. 1997)* (holding hospital immune from monetary damages); *Tabora v. Gottlieb Mere'l Hosp., 664 N.E.2d 267, 272 (Ill. App. Ct. 1996)* (holding hospital immune); *Gureasko v. Bethesda Hosp., 689 N.E.2d 76, 80 (Ohio Ct. App. 1996)* (holding hospital qualified for immunity); *Eyring v. Fort Sanders Parkwest Med. Ctr., Inc., 991 S. W.2d 230, 234-36 (Tenn. 1999)* (holding qualified immunity available to hospital).

n504. See, e.g., *Colo. Rev. Star. Ann. 12-36.5-104(4, 7,* 8) (West 1999) (establishing peer review procedural rights); *D.C. Code Ann. 32-1307* (Michie 1998) (providing standards for privileges and staff membership; procedural rights); *Fla. Stat. Ann. 395.0191 (4)-(6),* 395.0193(3) (West Supp. 2000)

(establishing eligibility criteria and grounds for adverse action); *210 Ill. Comp. Stat. Ann. 85/10.4(b)* (West Supp. 2000) (outlining minimum procedures for applicants and action concerning existing privileges); *Ind. Code Ann. 16-21-2-5(3)* (West Supp. 2000) (listing standards for appointment and continued membership); *Md. Code Ann. Health-Gen. H 19-319(e)* (Supp. 1996) (establishing minimum standards for credentialing process); *Neb. Rev. Stat. Ann. 71-2048.01* (1997) (requiring establishment of reasonable standards and application procedures); *Tex. Health & Safety Code Ann. 241.101(c)* (West Supp. 2000) (requiring procedural due process for medical staff applicants); *Va. Code Ann. 32.1-134.1* (Michie 1997) (detailing appropriate grounds for exclusion or expulsion of physician).

n505. See, e.g., *Colo. Rev. Stat. Ann. 12-36.5-104(4, 7, 8)* (1999); *D.C. Code 32-1307* (Michie 1998); *210 Ill. Comp. Star. Ann. 85/10.4(b)* (West Supp. 2000).

n506. The Texas statute, for example, states:

(c) The process for considering applications for medical staff membership and privileges or the renewal, modification or revocation of medical staff membership and privileges must afford each physician, podiatrist, and dentist procedural due process.

(d) An applicant for medical staff membership or privileges may not be denied membership or privileges on any ground that is otherwise prohibited by law.

Tex. Health & Safety Code Ann. 241.101(c), (d) (West Supp. 2000).

n507. Compare *Brooks v. Arlington Hosp. Ass'n, 850 F.2d 191, 198 (4th Cir. 1988)* (stating under Virginia statute, physician entitled to written statement of reasons for

suspension and review if reasons stated not allowed by statute), and *Lake Hosp. & Clinic, Inc. v. Silversmith, 551 So. 2d 538, 544 (Fla. Dist. Ct. App. 1989)* (finding physician has statutory due process claim), with *Wong v. Garden Park Cmty. Hosp., Inc., 565 So. 2d 550, 552 (Miss. 1990)* ("The legislature has clearly limited judicial surveillance of hospital disciplinary proceedings to the narrow inquiry of whether the hospital complied with the procedural due process requirements prescribed by its own bylaws."), and *Medical Ctr. Hosps. v. Terzis, 367 S.E.2d 728, 729-30 (Va. 1988)* (stating review limited to consideration of factors listed in statute).

n508.205 *N.Y.S. 554 (N. Y. App. Div. 1924)*, affd, *147 N.E. 219 (N..Y. 1925)*. See also *Leider v. Beth Israel Hosp. Ass'n, 182 N.E.2d 393 (N. Y. 1962)* (finding the board of trustees may not be restricted in the exercise of the sweeping powers the constitution commits to them).

n509. *Guibor v. Manhattan Eye, Ear & Throat Hosp., Inc., 386 N.E.2d 247, 247 (N. Y. 1978)*. The rule also applied to the termination of privileges. See *Cohoes Mem'l Hosp. v. Department of Health, 399 N.E.2d 1132, 1134 (N. Y. 1979)* (discussing old rule).

n510. N.Y. Pub. Health 2801-b(1) (West Supp. 2000).

n511. See N.Y. Pub. Health 2801-c (West Supp. 2000) (providing injunctive relief). See also, e.g., *Johnson v. Nyack Hosp., 964 F.2d 116, 121 (2d Cir. 1992)* (discussing New York statute which requires complaint be filed with PHC public health counsel); *Rose v. Taddonio, 934 F. Supp. 593, 595 (S.D.N.Y. 1996)* (discussing New York statute which requires physician to exhaust all remedies through PHC even for injunctive relief); *Gelbard v. Genesee Hosp., 664 N.E.2d 1240, 1242 (N. Y. 1996)* (outlining two-step process set forth by legislature where physician may seek injunctive relieve); *Fritz v. Huntington Hosp., 348 N.E.2d 547, 553-54 (N. Y. 1976)*

(recognizing under CPLR 103(c) relief includes injunctive action); *Guibor, 386 N.E.2d at 248* (holding CPLR 103(c) allows injunctive action); *Wee v. City of Rome, 649 N. Y.S.2d 614, 615 (N. Y. App. Div. 1996)* (stating injunction "exclusive remedy"); *Wollman v. Long Island Jewish Med. Ctr., 566 N. Y.S.2d 937, 939 (N. Y. App. Div. 1991)* (stating injunctive relief available under Public Health Law Section 2801-b); *Jackaway v. Northern Dutchess Hosp., 526 N. Y.S.2d 599, 599 (N. Y. App. Div. 1988)* (explaining plaintiff sought injunctive relief).

n512. See *West Coast Hosp. Ass°n v. Hoare, 64 So. 2d 293, 299 (Fla. 1953)* (holding rules and regulations applied to public hospitals not applicable to private hospitals).

n513. *Fla. Stat. Ann. 395.0191,* 395.0193 (West Supp. 2000). See also *Lake Hosp. & Clinic, Inc. v. Silversmith, 551 So. 2d 538, 544 (Fla. Dist. Ct. App. 1989)* (recognizing that adoption of 395.065(2) made private hospitals accountable for regulation of staff privileges). The state also has promulgated corresponding regulations governing hospital staff membership decisions and peer review. See Fla. Admin. Code Ann. r. 59A-3.201 (West, WESTLAW through July 1, 2000) (defining terms used in various state administrative regulations concerning management of hospital, organizational structure of medical staff, and peer review procedures); id. at 3.220 (requiring hospitals to have organized medical staff and bylaws, as well as rules and regulations that govern selection and retention of medical staff).

n514. *Fla. Star. Ann. 395.0191 (4)-(6),* 395.0193 (2), (3) (West Supp. 2000). See also *Silversmith, 551 So. 2d at 544* (recognizing statute requires private hospitals to be accountable for staffing privileges); *Lawler v. Eugene Wuesthoff Mem'l Hosp. Ass'n, 497 So. 2d 1261, 1264 (Fla. Dist. Ct. App. 1986)* (purpose of statute was to create conformity

and fairness in private hospital staffing decisions); *Carida v. Holy Cross Hosp., Inc., 427 So. 2d 803, 805 (Fla. Dist. Ct. App. 1983)* (explaining statute eliminates private/public distinction with regard to staff privileges).

n515. See *Fernandez v. Coral Gables Hosp., Inc., 720 So. 2d 1161, 1162-63 (Fla. Dist. Ct. App. 1998)* (discussing statute allows for injunctive relief); *Silversmith, 551 So. 2d at 544* (stating statute, not constitutional due process, provides basis for physician's claim); *Lawler, 497 So. 2d at 1264-65* (incorporating statute and explaining hospitals immune from liability as long as decisions conform with statute and not malicious); *Dam v. Heart of Fla. Hosp., Inc., 536 So. 2d 1177, 1178 (Fla. Dist. Ct. App. 1989)* (statute provides procedure for terminating privileges); *Carida, 427 So. 2d at 806 & n.6* (interpreting statute and concluding inadequate notice of termination would violate statute); cf. *Noble v. Martin Mem'l Hosp. Ass'n., 710 So. 2d 567, 569 (Fla. Dist. Ct. App. 1997)* (dismissing damage claims based on failure to allege "intentional fraud" as required by statute).

n516. See *Ariz. Rev. Stat. Ann. 36-445.02(B)* (West 1993) (stating judicial review limited to record with injunction as only remedy); *Cal. Civ. Pro. Code 1094.5(a)*, (d), (h) (West Supp. 2000) (providing for judicial review); *Colo. Rev. Stat. 12-36.5-106 (10)* (1999) (declaring administrative action may be reviewed by a court of appeals); *D.C. Code 32-1309(c)* (Michie Supp. 2000) (stating aggrieved party may bring action in superior court); N.Y. Pub. Health 2801-c (West 1993) (providing injunction relief by the courts); *Va. Code Ann. 32.1-134.1* (Michie 1997) (outlining right to injunctive relief by court); cf. *Fla. Stat. Ann. 395.0191 (9)*, 395.0193 (9) (West Supp. 2000) (providing attorney's fees).

n517. *Va. Code Ann. 32.1-134.1* (Michie 1997).

n518. Id.

n519. Id.

n520. *Ariz. Rev. Stat. Ann. 36-445.02(B)* (West 1993).

n521. Id.

n522. *Cal. Civ. Pro, Code 1094.5(a)* (West Supp. 2000).

n523. Id. 1094,5(d).

n524. Id. 1094.5(h).

n525. *D.C. Code 32-1307(b),* 1390(c) (Michie 1998).

n526. Id. 32-1307(c) (Michie 1998).

n527. *Colo. Rev. Stat. 12-36.5-106 (lO)(a),* (b) (1999); N.Y. Pub. Health 2801-c (West 1993).

n528. *Colo. Rev. Star. 12-36.5-106* (1999); N.Y. Pub. Health 2801-c (West 1993).

n529. N.Y. Pub. Health 2801-b(2) (West 1993).

n530. N.Y. Pub. Health 2801-b(2) (West 1993). See also *Gelbard v. Genesee Hosp., 664 N.E.2d 1240, 1242-43 (N. Y. 1996)* (holding "physician must submit a complaint to the Public Health Council" before bringing an action of injunctive relief). The Public Health Council is composed of the State Commissioner of Health and 14 persons appointed by the governor with the advice and consent of the state senate. N.Y. Pub, Health 220 (West 1990).

n531. N.Y. Pub. Health 2801-b(3) (West 1993). See also *Gelbard, 664 N.E.2d at 1242* (discussing and explaining requirements of statute).

n532. N.Y. Pub. Health 2801-c (West 1993). See also *Gelbard, 664 N.E.2d at 1243* (plaintiff may bring action for injunctive relief to restore privileges only after PHC review but noting, without elaborating, that some claims may not be subject to requirement of PHC review).

n533. *Gelbard, 664 N.E.2d at 1243.*

n534. N.Y. Pub. Health 2801-c (West 1993).

n535. Id. See also *Gelbard, 664 N.E.2d at 1242* ("PHC's determination serves as prima facie evidence of the facts found therein" but "findings are accorded only presumptive, not conclusive, effect.").

n536. *Colo. Rev. Stat. 12-36.5-106* (1999).

n537. Id. The fifth member must be a licensed attorney with experience in antitrust law. Id. 12-36.5-106(2).

n538. Id. 12-36.5-106(7).

n539. Id. 12-36.5-106(9)(k)-(m).

n540. Id. 12-36.5-106(10). See also *Northern Colorado Med. Ctr., Inc. v. Committee on Anticompetitive Conduct, 914 P.2d 902, 905-06 (Colo. 1996)* (citing statute as support for appellate review); *Nicholas v. Northern Colorado Med. Ctr., Inc., 902 P.2d 462, 466 (Colo. Ct. App. 1995)* (stating statute "expressly confers a right to seek judicial review"), affd sub nom. *Northern Colo. Med. Ctr., Inc. v. Committee on Anticompetitive Conduct, 914 P.2d 902 (Colo. 1996).*

n541. *Colo. Rev. Stat. 12-36.5-106(8)* (1999). Claims of anticompetitive conduct that do not result from professional review committee activity also may be raised directly in a court. See Ryals v. St. Mary-Corwin Reg'l Med. Ctr., No. *99SC137, 2000 WL 1335873, at 1* (Colo. Sept. 18, 2000)

(holding Committee on Anticompetitive Conduct did not have jurisdiction over claims where denial of privileges was business decision not involving physician's qualifications or conduc0.

n542. See, e.g., *Kiester v. Humana Hosp. Alaska, Inc., 843 P.2d 1219, 1223 (Alaska 1992)* (granting hospital governing body great deference regarding applications for hospital privileges); *Owens v. New Britain Gen. Hosp., 643 A.2d 233, 241 (Conn. 1994)* (noting that courts should usually defer to hospital board's decisions); *Dworkin v. St. Francis Hosp., Inc., 517 A.2d 302, 305 (Del. Super Ct. 1986)* (same); *Nanavati v. Burdette Tomlin Mem'l Hosp., 526 A.2d 697, 702-03 (N.J. 1987)* (same); *Mahmoodian v. United Hosp. Ctr., Inc., 404 S.E.2d 750, 756 (W. Va. 1991)* (same).

n543. See *Kiester, 843 P.2d at 1223* (referring to "a hospital's recognized expertise regarding evaluation of medical qualifications"); *Owens, 643 A.2d at 241* (noting that determinations of professional competence "should be left to the expertise of the hospital's staff and administration").

n544. See, e.g., *Even v. Longmont United Hosp. Ass'n, 629 P.2d 1100, 1102 (Colo. Ct. App. 1981)* (evaluating substantial compliance to bylaws); *Owens, 643 A.2d at 241-42 & n.28* (reviewing substantial compliance of hospital bylaws); *Stiller v. La Porte Hosp., Inc., 570 N.E.2d 99, 103 (Ind. Ct. App. 1991)* (limiting court's role to determining substantial compliance to bylaws); *Smith v. Our Lady of the Lake Hosp., Inc., 639 So. 2d 730, 755 (La. 1994)* (applying substantial compliance standard to hospital's adherence to bylaws); *Babcock v. St. Francis Med. Ctr., 543 N. W.2d 749, 761 (Neb. Ct. App. 1996)* (same); *Brinton v. IHC Hosps., Inc., 973 P.2d 956, 964-65 (Utah 1998)* (same); *Mahmoodian, 404 S.E.2d at 756* (same). But see *Berberian v. Lancaster Osteopathic Hosp. Ass'n, 149 A.2d 456, 459 (Pa. 1959)* (implying strict compliance standard); *Miller v. Indiana Hosp., 419 A.2d 1191,*

d193 (Pa. Super. Ct. 1980) (requiring strict compliance to bylaws).

n545. See *Brinton, 973 P.2d at 964* (allowing procedural fairness to be questioned, but refusing to evaluate medical judgment of hospital).

n546. See *Kiester, 843 P.2d at 1223* (stating "courts are equipped to determine whether a hospital governing body has followed its bylaws and whether a decision regarding an application for privileges was made in accordance with basic principles of fairness and due process"); *Owens, 643 A.2d at 241* (limiting review to considerations of basic notice and fair hearing procedures).

n547. See Cal. Code Civ. Pro. 1094.5(d) (West Supp. 2000) (establishing abuse of discretion standards; findings not supported by substantial evidence); *Sokol v. Akron Gen. Med. Ctr., 173 F.3d 1026, 1030 (6th Cir. 1999)* (reviewing for arbitrariness, abuse of discretion, supported by any evidence); *Kiester, 843 P.2d at 1223* (ensuring standards set by hospital not arbitrary and capricious); *Holmes v. Hoemako Hosp., 573 P.2d 477, 478-79 (Ariz. 1977)* (ensuring hospital rules not arbitrary and capricious); *Oskooi v. Fountain Valley Reg'l Hosp. &Med. Ctr., 49 Cal. Rptr. 2d 769, 774 (Cal. Ct. App. 1996)* (requiring substantial evidence); *Hawkins v. Kinsie, 540 P.2d 345, 349 (Colo. Ct. App. 1975)* (stating claim if decision is arbitrary, capricious, and unreasonable); *Dworkin v. St. Francis Hosp., Inc., 517 A.2d 302, 305-06 (Del. Super. Ct. 1986)* (confining court's role to determination of whether review committee decision was arbitrary or capricious); *Babcock, 543 N. W.2d at 760* (sufficient evidence, not arbitrary or capricious); *Nanvati v. Burdette Tomlin Mem'l Hosp., 526 A.2d 697, 702 (N.J. 1987)* (passing judicial review when decision supported by sufficient reliable evidence); *Guerrero v. Burlington County Mem'l Hosp., 360 A. 2d 334, 340 (N. J. 1976)* (determining whether decision supported by credible evidence, not arbitrary or capricious); *Bouquett v. St.*

Elizabeth Corp., 538 N.E.2d 113, 114 (Ohio 1989) (refraining from interfering unless decision was arbitrary, capricious, unreasonable, i.e., an abuse of discretion); *Mahmoodian, 404 S.E.2d at 762* (applying substantial evidence standard).

n548. *Babcoc& 543N.W.2d at 760.*

n549. See supra notes 89-168 and accompanying text for a discussion of these competing interests.

n550. Groseclose, supra note 90, at 2.

n551. See generally supra Part III for a discussion of the various theories of review.

n552. See supra note 173 and accompanying text for a discussion judicial review of public hospital actions.

n553. See generally supra Part III for a discussion of these various theories of review.

n554. See supra notes 270, 288 and accompanying text discussing review of decisions excluding physicians.

n555. See supra notes 448-548 and accompanying text for a discussion of these theories.

n556. See supra notes 159-60, 542-48 and accompanying text for a discussion of the deference courts afford hospital decisions.

n557. See supra note 547 and accompanying text for a discussion of standard of review.

n558. See, e.g., *Janda v. Madera Cmty. Hosp., 16 F. Supp. 2d 1181, 1186 (E.D. Cal. 1998)* (finding, under California law, physician can enjoin hospital); *Adkins v.*

Sarah Bush Lincoln Health Ctr., 544 N.E.2d 733, 737 (Ill. 1989) (holding physician properly reinstated).

n559. See supra notes 159-60, 542-48 and accompanying text discussing deference courts afford hospital decisions.

n560. *Oskooi v. Fountain Valley Reg'l Hosp. & Med. Ctr., 49 Cal. Rptr. 2d 769, 776 (Cal. Ct. App. 1996)* (Sills, J., concurring).

n561. See supra notes 379-416 and accompanying text discussing contract theory.

(5) 04 312 AUG 31 2004

No. OFFICE OF THE CLERK

In The Supreme Court of the United States

AMERICAN CHIROPRACTIC ASSOCIATION, INCORPORATED, a non-profit corporation, *et al.*,

Petitioners,

v.

TRIGON HEALTHCARE, INCORPORATED, *et al.*,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

APPENDIX A (VOL. III OF III) TO
PETITION FOR WRIT OF CERTIORARI

George P. McAndrews
Counsel of Record
Steven J. Hampton
Patrick J. Arnold, Jr.
Sharon Hwang
James P. Murphy
Peter J. McAndrews
Ronald A. Dicerbo
MCANDREWS, HELD & MALLOY, LTD.
34th Floor
500 West Madison Street
Chicago, IL 60661
(312) 775-8000

Thomas R. Daly
ODIN, FELDMAN, & PITTLEMAN, P.C.
9032 Lee Highway
Suite 1100
Fairfax, VA 22031
(703) 218-2100

William G. Shields
THORSEN & SCHER
3810 Augusta Ave.
Richmond, VA 23230
(804) 359-3000

Counsel for Petitioners

THE LEX GROUP ♦ 1108 East Main Street ♦ Suite 1400 ♦ Richmond, Virginia 23219
(804) 644-4419 ♦ (800) 856-4419 ♦ Fax: (804) 644-3660 ♦ www.thelexgroup.com

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Clinical Practice Guideline
Number 14

Acute Lower Back Problems in Adults

U.S. Department of Health and Human Services
Public Health Service
Agency for Health Care Policy and Research

The Agency for Health Care Policy and Research (AHCPR) was established in December 1989 under Public Law 101-239 (Omnibus Budget Reconciliation Act of 1989) to enhance the quality, appropriateness, and effectiveness of health care services and access to these services. AHCPR carries out its mission by conducting and supporting general health services research, including medical effectiveness research, facilitating development of clinical practice guidelines, and disseminating research findings and guidelines to health care providers, policymakers, and the public.

The legislation also established within AHCPR the Office of the Forum for Quality and Effectiveness in Health Care (the Forum). The Forum has primary responsibility for facilitating the development, periodic review, and updating of clinical practice guidelines. The guidelines will assist practitioners in the prevention, diagnosis, treatment, and management of clinical conditions.

Other AHCPR components include the following. The Center for Medical Effectiveness Research has principal responsibility for patient outcomes research and studies of variations in clinical practice. The Center for General Health Services Extramural Research supports research on primary care, the cost and financing of health care, and access to care for underserved and rural populations. The Center for General Health Services Intramural Research uses large data sets for policy research on national health care expenditures and utilization, hospital studies, and long-term care. The Center for Research Dissemination and Liaison produces and disseminates findings from AHCPR-supported research, including guidelines, and conducts research on dissemination methods. The Office of Health Technology Assessment responds to requests from Federal health programs for assessment of health care technologies. The Office of Science and Data Development develops

specialized databases and enhances techniques for using existing databases for patient outcomes research.

Guidelines are available in formats suitable for health care practitioners, the scientific community, educators, and consumers. AHCPR invites comments and suggestions from users for consideration in development and updating of future guidelines. Please send written comments to Director, Office of the Forum for Quality and Effectiveness in Health Care, AHCPR, Willco Building, Suite 310, 6000 Executive Boulevard, Rockville, MD 20852

Acute Lower Back Problems in Adults

Stanley J. Bigos, MD (Chair)
Rev. O. Richard Bowyer
G. Richard Braen, MD
Kathleen Brown, PhD, RN
Richard Deyo, MD, MPH
Scott Haldeman, DC, MD, PhD
John L. Hart, DO
Ernest W. Johnson, MD
Robert Keller, MD
Daniel Kido, MD, FACR
Matthew H. Liang, MD, MPH
Roger M. Nelson, PT, PhD
Margareta Nordin, RPT, DrSci
Bernice D. Owen, PhD, RN
Malcolm H. Pope, DrMedSc, PhD
Richard K. Schwartz, MS, OTR, FSR
Donald H. Stewart, Jr., MD
Jeff Susman, MD
John J. Triano, MA, DC
Lucius C. Tripp, MD, MPH, FACPM
Dennis C. Turk, PhD
Clark Watts, MD, JD
James N. Weinstein, DO

U.S. Department of Health and Human Services
Public Health Service

Agency for Health Care Policy and Research
Rockville, Maryland

AHCPR Publication No. 95-0642
December 1994

Guideline Development and Use

Guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care. This guideline was developed by an independent multidisciplinary panel of private-sector clinicians and other experts convened by the Agency for Health Care Policy and Research (AHCPR). The panel employed explicit, science-based methods and expert clinical judgment to develop specific statements on acute low back problems in adults.

Extensive literature searches were conducted and critical reviews and syntheses were used to evaluate empirical evidence and significant outcomes. Peer review and field review were undertaken to evaluate the validity, reliability, and utility of the guideline in clinical practice. The panel's recommendations are primarily based on the published scientific literature. When the scientific literature was incomplete or inconsistent in a particular area, the recommendations reflect the professional judgment of panel members and consultants.

The guideline reflects the state of knowledge, current at the time of publication. Given the inevitable changes in the state of scientific information and technology, periodic review, updating, and revision will be done.

We believe that the AHCPR-assisted clinical guidelines will make positive contributions to the quality of care in the United States. We encourage practitioners and patients to use the information provided in this *Clinical Practice Guideline*. The recommendations may not be appropriate for use in all circumstances. Decisions to adopt any particular recommendation must be made by the practitioner in light of available resources and circumstances presented by individual patients.

Clifton R. Gaus, ScD
Administrator
Agency for Health Care Policy and Research

Publication of this guideline does not necessarily represent an endorsement by the U.S. Department of Health and Human Services

Abstract

Findings and recommendations on the assessment and treatment of adults with acute low back problems-activity limitations due to symptoms in the low back and/or back-related leg symptoms of less than 3 months' duration-are presented in this clinical practice guideline. The following are the principal conclusions of this guideline:

- The initial assessment of patients with acute low back problems focuses on the detection of "red flags" (indicators of potentially serious spinal pathology or other nonspinal pathology).

- In the absence of red flags, imaging studies and further testing of patients are not usually helpful during the first 4 weeks of low back symptoms.

- Relief of discomfort can be accomplished most safely with nonprescription medication and/or spinal manipulation.

- While some activity modification may be necessary during the acute phase, bed rest >4 days is not helpful and may further debilitate the patient.

- Low-stress aerobic activities can be safely started in the first 2 weeks of symptoms to help avoid debilitation; exercises to condition trunk muscles are commonly delayed at least 2 weeks.

- Patients recovering from acute low back problems are encouraged to return to work or their normal daily activities as soon as possible.

- If low back symptoms persist, further evaluation may be indicated.

- Patients with sciatica may recover more slowly, but further evaluation can also be safely delayed.

- Within the first 3 months of low back symptoms, only patients with evidence of serious spinal pathology or severe, debilitating symptoms of sciatica, and physiologic evidence of specific nerve root compromise corroborated on imaging studies can be expected to benefit from surgery.

- With or without surgery, 80 percent of patients with sciatica recover eventually.

- Nonphysical factors (such as psychological or socioeconomic problems) may be addressed in the context of discussing reasonable expectations for recovery.

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Bigos S, Bowyer O, Braen G, et al. Acute Low Back Problems in Adults. Clinical Practice Guideline No. 14. AHCPR Publication No. 95-0642. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services. December 1994.

Panel Members

Stanley J. Bigos, MD, *Chair*
University of Washington
Seattle, Washington
Orthopedic Surgeon

Reverend O. Richard Bowyer
Fairmont State College
Fairmont, West Virginia
Consumer Representative

G. Richard Braen, MD
State University of New York
Buffalo, New York
Emergency Medicine Physician

Kathleen Brown, PhD, RN
University of Alabama
Birmingham, Alabama
Occupational Health Nurse

Richard Deyo, MD, MPH
University of Washington
Seattle, Washington
General Internist

Scott Haldeman, DC, MD, PhD
University of California at Irvine
Santa Ana, California
Neurologist/Chiropractor

John L. Hart, DO
Still Regional Medical Center
Columbia, Missouri
Physiatrist

Ernest W. Johnson, MD
Ohio State University
Columbus, Ohio
Physiatrist

Robert Keller, MD
Maine Medical Assessment Foundation
Belfast, Maine
Orthopedic Surgeon

Daniel Kido, MD, FACR
Washington University Medical Center
St. Louis, Missouri
Radiologist

Matthew H. Liang, MD, MPH
Harvard Medical School
Boston, Massachusetts
Rheumatologist

Roger M. Nelson, PT, PhD
Thomas Jefferson University
College of Allied Health Sciences
Philadelphia, Pennsylvania
Physical Therapist

Margareta Nordin, RPT, DrSci
Hospital for Joint Diseases
New York, New York
Physical Therapist/Orthopedic Researcher

Bernice D. Owen, PhD, RN
University of Wisconsin
Madison, Wisconsin
Community Health Nurse

Malcolm H. Pope, DrMedSc, PhD
University of Vermont
Burlington, Vermont
Orthopedic Researcher

Richard K. Schwartz, MS, OTR, FSR
San Antonio, Texas
Occupational Therapist

Donald H. Stewart, Jr., MD
Arlington, Virginia
Neurosurgeon

Jeff Susman, MD
University of Nebraska Medical Center
Omaha, Nebraska
Family Physician

John J. Triano, MA, DC
Texas Back Institute
Plano, Texas
Chiropractor

Lucius C. Tripp, MD, MPH, FACPM
General Motors-Henry Ford
Hospital Rehabilitation Center
Warren, Michigan
Neurosurgeon/Occupational Medicine Specialist

Dennis C. Turk, PhD
University of Pittsburgh School of Medicine
Pittsburgh, Pennsylvania
Psychologist

Clark Watts, MD, JD
University of Texas Health Sciences Center
San Antonio, Texas
Neurosurgeon

James N. Weinstein, DO
University of Iowa Hospitals
Iowa City, Iowa
Orthopedic Surgeon

Executive Summary

Acute low back problems, the subject of this *Clinical Practice Guideline,* are experienced by almost everyone at some time in their adult lives. Back problems rank high among the reasons for physician office visits and are costly in terms of medical treatment, time lost from work, and nonmonetary costs such as diminished ability to perform or enjoy usual activities. For persons under age 45, low back problems are the most frequent cause of disability.

The Agency for Health Care Policy and Research (AHCPR) convened a 23-member, multidisciplinary, private-sector panel to develop a guideline for the evaluation and treatment of acute low back problems in adults. The panel included physicians, nurses, chiropractors, experts in spine research, physical therapists, a psychologist, an occupational therapist, and a consumer representative. The panel defined back problems as activity intolerance due to back-related symptoms and acute as limitations of less than 3 months' duration. Back symptoms include pain, primarily in the back, as well as back-related leg pain (sciatica). The panel agreed that the guideline should provide primary care clinicians with information on the detection of serious spinal pathology (such as tumor or infection, spinal fracture or cauda equina syndrome) as well as nonspinal pathology that could be causing limitations due to low back symptoms, but that treatment of these conditions is outside the scope of the guideline.

Furthermore, the panel agreed that the assessment and treatment of patients younger than 18 years or those with chronic low back problems (back-related limitations lasting longer than 3 months) may be quite different than for adults with acute problems. For this reason, the panel decided that back problems in children as well as chronic low back problems are also outside the scope of the guideline.

The panel's overall intent was to change the paradigm of focusing care exclusively on the pain of low back problems to one of helping patients improve their activity tolerance. Findings and recommendation statements are based on an exhaustive and systematic review and analysis of the scientific literature as well as information gathered from the clinical experience of the expert panel, public testimony, peer review, and pretesting in outpatient settings. This guideline is divided into an introduction and three chapters to correlate with the clinical approach: (1) Initial Assessment

Methods; (2) Clinical Care Methods; and (3) Special Studies and Diagnostic Considerations.

Initial Assessment Methods

The initial assessment of a patient with activity intolerance due to low back symptoms consists of a focused medical history and physical examination. The primary purpose is to seek medical history responses or physical examination findings that suggest a serious underlying spinal condition such as fracture, tumor, infection, or cauda equina syndrome. These responses or findings are referred to as "red flags." The history and physical examination should also assess for nonspinal conditions (vascular, abdominal, urinary, or pelvic pathology) causing referred low back symptoms.

Once the clinician has ruled out red flags and nonspinal pathology, the symptoms can be categorized as either sciatica or nonspecific back pain. In the absence of red flags, neither routine nor special testing is required in the first month of symptoms for either category. Most of these patients will recover spontaneously from their activity limitations within 1 month.

Clinical Care Methods

In the absence of the red flags described above, most patients with activity intolerance due to an acute episode of low back symptoms can be treated similarly during the first month. The goals are to provide patients with accurate information about low back problems, assist with symptom relief, and make appropriate activity recommendations.

Once the history and physical examination are complete, the patient can be assured that there is no hint of a dangerous medical condition causing the back problem and

that a rapid recovery is expected. Symptom control methods focus initially on providing the patient with a comfort level adequate to keep the patient as active as possible while awaiting spontaneous recovery. Later in treatment, symptom control is considered an adjunct in helping the patient overcome a specific activity intolerance. The primary methods of symptom control are oral pharmaceuticals and physical methods.

Among the oral medications available to control the discomfort of acute low back problems, the panel recommends acetaminophen as reasonably safe and acceptable. Nonsteroidal anti-inflammatory drugs (NSAIDs), including aspirin, are also acceptable despite the potential for side effects, most frequently gastrointestinal irritation. Muscle relaxants, including benzodiazepines, have been found no more effective than NSAIDs in treating patients with acute low back problems, and potential side effects of these drugs include drowsiness in up to 30 percent of patients. The panel recommended that opioids be avoided if possible because of significant risks of debilitation, drowsiness, decreased reaction time, clouded judgment, and potential misuse. If chosen, they should be used only for a short time. The panel also recommended against the use of oral steroids, colchicine, or antidepressant medications for acute low back problems.

The panel found manipulation to be a recommendable method of symptom control. Manipulation seems helpful for patients with acute low back problems without radiculopathy when used within the first month of symptoms. If no symptomatic and functional improvement has been noted after 1 month of manipulative therapy, this treatment should be stopped and the patient reevaluated. The panel found no evidence of benefit from the application of physical agents and modalities such as ice, heat, massage, traction, ultrasound, cutaneous laser treatment,

transcutaneous electrical nerve stimulation (TENS), and biofeedback techniques. Self-application of heat or cold may be taught to patients who choose such options to provide temporary relief of symptoms. Evidence does not support the use of trigger point, ligamentous and facet joint injections, needle acupuncture, or dry needling as treatment for acute low back problems.

The panel found that prolonged bed rest (for more than 4 days) may lead to debilitation and is not appropriate in the treatment of acute low back problems. A gradual return to normal activities is advisable, although bed rest for 2 to 4 days may be an option for patients with severe initial symptoms of sciatica. The patient whose symptoms are aggravated by lifting or prolonged sitting may require specific advice and exploration of alternatives. For most patients, aerobic activities that minimally stress the back (such as walking, biking, or swimming) can be started during the first 2 weeks of acute low back problems. After this, conditioning exercises for trunk muscles (in particular back extensors) may be helpful, especially if the patient's acute low back problems persist, although such exercises may initially aggravate symptoms.

Special Studies and Diagnostic Considerations

The panel recommended that clinicians consider a diagnostic reevaluation that may include special studies if the patient continues to be limited by back symptoms for more than 1 month without improvement. This reevaluation begins with a review and update of the history and physical exam to look again for red flags or evidence of nonspinal conditions causing back symptoms. If none of these is found, an appropriate evaluation can be initiated for either patients with sciatica or those with nonspecific low back symptoms.

For patients limited by sciatica for more than 4 weeks without clear evidence on physical examination of nerve root compromise, electromyography (EMG) and H-reflex tests of the lower limb may provide evidence of suspected neurologic dysfunction. Sensory evoked potentials (SEPs) may be a useful adjunct for assessment of suspected spinal stenosis or spinal cord myelopathy. For patients limited by sciatica for more than 4 weeks with physiologic evidence of neurologic dysfunction, MRI or CT is an appropriate consideration to provide anatomic definition of suspected herniated disc before surgery. Anatomic abnormalities of the lumbar spine (such as degenerative changes or abnormal discs) can be confusing since they increase in frequency as patients age and are often noted on imaging tests in subjects with no symptoms of low back problems. Abnormalities on imaging should corroborate evidence from physical examination or physiologic testing. A referral for surgical consultation is reasonable for patients with sciatic symptoms who have (1) activity limitations for more than 1 month without improvement, (2) clear clinical or electrophysiological evidence of nerve root compromise, and (3) corroborative findings on imaging studies. Earlier emergency consultation is reserved for patients with findings of bowel and/or bladder dysfunction or progressive and/or severe neurologic impairment. Most patients with symptoms persisting beyond 4 weeks will not be surgical candidates since the majority will have nonspecific acute low back symptoms without evidence of a serious underlying condition.

Following diagnostic or surgical procedures, treatment for those patients who have not recovered focuses on graduated physical conditioning to gain tolerance for activities required at home and/or the workplace. To help patients who have extreme difficulty overcoming their personal activity intolerance, clinicians are encouraged to address any nonphysical factors (such as unrealistic

expectations by patient or employer or other psychosocial problems) that can potentially be influenced in a positive manner. The goal is to help the patient recover normal activity tolerance and avoid the development of a chronic low back disability.

1. Overview

Purpose and Rationale

There are four principal reasons acute low back problems were selected as a subject for guideline development. One reason is their prevalence. Most people report low back problems at some time in their lives, and national statistics indicate a general yearly prevalence in the U.S. population of 15-20 percent.[1] Among working-age people surveyed, 50 percent admit to back symptoms each year.[2,3] Back symptoms, in fact, are the most common cause of disability for persons under age 45.[4] At any given time, about 1 percent of the U.S. population is chronically disabled because of back problems, and another 1 percent temporarily disabled.[1]

A second reason for a guideline on assessment and treatment of acute low back problems is cost. Low back problems are expensive. Their total costs to society are difficult to calculate, but evidence indicates that both the economic and psychosocial costs are substantial. Low back problems are the second most common symptomatic reason expressed by patients for office visits to primary care physicians.[5] They are the most common reason for office visits to orthopedic surgeons, neurosurgeons, and occupational medicine physicians. They rank third among the reasons for surgical procedures.

Moreover, although medical costs are high, loss of time from work as well as the disability payments for work-related low back problems can together cost up to three

times as much as medical treatment.[6] About 2 percent of the U.S. work force has compensable back problems each year.[7] Various estimates of the total annual societal cost of back pain in the United States range from $20 to $50 billion.[8] Nonmonetary costs of low back problems can also be substantial. The inability to function normally at work and in other daily activities has an impact on both patients and their families.

A third important reason for this guideline is the increasing evidence that many patients with activity intolerance due to low back symptoms may be receiving care that is inappropriate or at least less than optimal. Rates for hospitalization and surgery for low back problems vary substantially among regions of the United States as well as among small areas within states.[9-11] Marked regional variations also occur in the use of diagnostic tests for assessing low back problems.[9] These variations imply a lack of consensus about appropriate assessment and treatment of low back problems, suggesting that some patients may be receiving inappropriate or suboptimal care.

In addition, some patients appear to be more disabled after treatment than before, another potential indicator of suboptimal care. Perhaps the most obvious examples involve surgery. Despite an extensive medical literature on failed back surgery and evidence that repeat surgical procedures for low back problems rarely lead to improved outcome, there are documented examples of patients who have had as many as 20 spine operations.[9] However, surgery is not the only treatment that can lead to increased disability. Common treatment methods such as extended bed rest or extended use of high-dose opioids can prolong symptoms and further debilitate patients.

A fourth reason for the guideline is a growing body of research on low back problems, allowing a systematic

evaluation of commonly used assessment and treatment methods. Although the existing literature has shortcomings, there is sufficient scientific evidence for a number of conclusions about the efficacy and safety of current assessment and treatment methods.

Scope and Organization

Scope

This *Clinical Practice Guideline* is intended to provide primary care clinicians with information and recommended strategies for the assessment and treatment of acute low back problems in adults. To develop this guideline, AHCPR convened a private-sector, multidisciplinary panel of clinicians, researchers, and a consumer representative to evaluate the scientific evidence in the medical literature, draw conclusions, and make recommendations.

In determining the scope of the guideline, the panel focused on information needed for primary care assessment and treatment of adults with acute low back problems. "Back problems" were defined as activity intolerance due to back-related symptoms and acute as limitations of less than 3 months' duration. Back symptoms include pain in the back as well as back-related leg pain (sciatica). The panel agreed that the guideline should provide information on initial detection of underlying serious conditions (such as fracture, tumor, infection, or cauda equina syndrome) that could be causing low back problems, but that treatment of these conditions is outside the scope of the guideline.

The panel agreed further that the assessment and treatment of patients who have chronic low back problems (with symptoms lasting over 3 months) may be quite different than for patients with acute problems. Patients who become disabled due to chronic low back problems

represent less than 5 percent of those with low back problems, but they account for up to 60 percent of the societal costs for this disorder.[6] To a much greater extent than acute problems, chronic low back problems are influenced by complex psychological, behavioral, socioeconomic, demographic, legal, and occupational factors, many of which are not easily controlled.[8] For these reasons, the panel decided that chronic low back problems are beyond the scope of a guideline on acute problems. The recommendations included in the guideline may not apply to persons younger than 18 years since diagnostic and treatment considerations for this group are often different than for adults.

Evaluation of Evidence. The panel agreed that this guideline on acute low back problems should be anchored to published scientific evidence, and that such evidence should take priority over panel opinion in making guideline recommendations. In looking at a proposed assessment or treatment method, the panel considered: (1) efficacy, (2) potential harms, and (3) costs.

The panel considered randomized controlled trials (RCTs) that focused on patient-oriented clinical outcome measures such as symptom relief or improved level of functioning to be the acceptable method for establishing the efficacy of treatment methods. Evidence about efficacy of assessment methods was considered adequate if results of the diagnostic test studied were compared to an independent reference standard in a way that allowed calculation of standard test parameters, such as the test's true-positive rate (sensitivity) and true-negative rate (specificity).

The panel agreed to give the greatest weight to scientific research evidence that met the above criteria. When such strong scientific evidence was not available, the panel

labeled the evidence as weak and indirect and used the combined expert opinion and clinical judgment of panel members for interpretation. In all cases, the guideline explicitly states the type of evidence used by the panel as the basis for recommendations. The scale used for labeling the evidence is at the end of this chapter.

Prevention Studies. The panel found that, to date, studies of interventions aimed at preventing low back problems or their risk factors present conflicting findings and explain only a small portion of back complaints. Few of these prevention studies have been well designed, and most have been conducted in workplace settings focusing on injury claims or have used interventions that could not easily be carried out by primary care providers. When information from these studies was applicable to primary care, however, it was included under specific areas of assessment or treatment in the guidelines.

The panel agreed that a methodological problem commonly associated with studies of the prevention of back problems is lack of precision in specifying the goal(s) of the preventive intervention. Researchers often fail to establish whether the goal is to prevent the first episode of low back symptoms, activity limitations, recurrent episodes, injury claims, time lost from work, chronic disability, and/or medical care utilization and costs. In addition, some authors have suggested that efforts to prevent first or recurrent episodes of low back symptoms at work may be futile, and that research should focus instead on preventing long-term disability that results in high-cost disability claims.[6,12,13]

Organization and Clinical Categories

Chapter 2 of this guideline focuses on the initial assessment of the patient with activity limitations due to acute low back symptoms, and Chapter 3 addresses initial

treatment methods for these patients. The assessment and treatment methods considered in these chapters can typically be managed by the primary care clinician. Up to 90 percent of patients with acute low back problems recover within 1 month from activity limitations due to symptoms.[6,14,15] Chapter 4 addresses diagnostic and treatment considerations for the small percentage of patients who still have substantial symptoms or limitations after 1 month. Many of these diagnostic and therapeutic methods can be managed by the primary care clinician; others will require consultation with a specialist.

The panel recognized that different clinical disciplines use a variety of diagnostic labels that implicitly suggest a cause for low back symptoms. However, these labels are often unreliable for categorizing causes of acute low back problems. Even after an extensive workup, only about 15 percent of patients can be given a definitive diagnosis.[16]

Since the many diagnostic labels currently used to describe low back problems may confuse patients and clinicians, the panel considered it more useful to classify a patient's acute low back problem into one of three descriptive clinical categories based on medical history and physical examination findings:

- **Potentially serious spinal condition:** spinal tumor, infection, fracture, or cauda equina syndrome suggested by findings from medical history or physical examination ("red flags").

- **Sciatica:** back-related lower limb symptoms suggesting nerve root compromise.

- **Nonspecific back symptoms:** symptoms occurring primarily in the back that suggest neither nerve root compromise nor a serious underlying condition.

In the panel's opinion, clinicians would have enough information to make appropriate decisions about initial assessment and treatment, as well as some hints about prognosis, after correctly classifying patients with low back problems into one of the above three categories. The panel used this classification scheme in making guideline recommendations about assessment and treatment methods.

Methodology for Guideline Development

The general theory and principles underlying development of clinical practice guidelines are presented in an Institute of Medicine report;[17] other reports published by AHCPR provide specific information on the clinical guideline development process.[18] These materials provided a starting point for developing the *Clinical Practice Guideline* on low back problems. AHCPR provided the general parameters for guideline development. The panel, aided by the methodologists and consultants, then independently determined the specific methodology for the project, directed the literature review, and developed the guideline findings and recommendations.

Formation of the Panel and Staff

AHCPR initiated formation of the panel and appointed its chairperson and members. Important considerations in the choice of panel members were: (1) demonstrated knowledge about low back problems, (2) representation of major clinical disciplines involved in back care, and (3) geographic diversity. Nominations were solicited through a *Federal Register* announcement and from professional and consumer organizations and persons interested in the care of patients with low back problems.

More than 200 individuals were nominated. AHCPR selected 23 representing the fields of biomechanical and

spine research, chiropractic care, emergency medicine, family medicine, internal medicine, neurology, neurosurgery, occupational health nursing, occupational medicine, occupational therapy, orthopedics, osteopathic medicine, physical and rehabilitation medicine, physical therapy, psychology, rheumatology, and radiology.

The panel also included a consumer representative who had experienced low back problems, but did not work in the health care field. Several consultants with expertise in spine research, clinical care of low back problems, clinical epidemiology, and health economics were appointed to the panel. Two methodologists with experience in developing clinical practice guidelines were assigned to the panel by AHCPR. Both methodologists were physicians with MPH degrees, one an emergency medicine physician and one an internist. The methodologists aided the panel in determining the scope of the literature search and the criteria to be used for selecting articles for panel review.

The panel chair formed a research and support staff that included two physicians: a spine-fellowship-trained orthopedic surgeon and an occupational-medicine-trained physician with an MPH degree. National Library of Medicine representatives aided the staff in retrieving literature. The staff screened articles and constructed evidence tables for articles according to panel review criteria. These evidence tables and the original articles were presented to the panel for review and interpretation. The panel used this information as the basis for its guideline findings and recommendations.

Public Comment and Peer Review

An open forum was held early in the guideline development process to give interested individuals, organizations, and agencies the opportunity to present

written or verbal testimony. Later in the process, drafts of the guideline were sent out for peer and pilot review. AHCPR selected peer and pilot reviewers from those who had expressed interest in the guideline, participated in the open forum, or were nominated by professional organizations or panel members.

Over 100 peer reviewers were selected based on their expertise in the care of low back problems. They were asked to evaluate the comprehensiveness of the literature review as well as the panel's findings and recommendations. The pilot reviewers who were selected represented a cross-section of primary care settings including private and group practices, health maintenance organizations, and occupational medicine clinics. They were asked to evaluate the practical applicability of the guideline in their own practice settings by using examples published in the *Quick Reference Guide for Clinicians* and by soliciting feedback from patients given the *Consumer Version*. The panel used comments from peer and pilot reviewers to guide final revisions of the guideline.

Literature Search

The panel initiated a comprehensive literature search of topics deemed applicable to low back problems. The Quebec Task Force on Spinal Disorders had previously published an evidence-based guideline on low back problems, based upon an exhaustive literature search through 1984.[19] The bibliography from their report was the starting point in the literature search for this AHCPR guideline.

The literature search of articles published after 1984 was performed through the National Library of Medicine. Abstracts of 10,317 articles which met the search criteria were each independently evaluated by the orthopaedic surgeon and occupational medicine physician on the

research staff. If either reviewer thought an article might be useful, the entire article was retrieved. A total of 3,918 articles (38 percent of all abstracts evaluated) was obtained for further evaluation.

Additional articles came from panel members, from the open forum process, and from unsolicited sources. All articles were entered in a comprehensive bibliography, classified by topic, and screened methodologically to determine if they contained information that might be useful to the panel.

Evaluation of Efficacy

In evaluating efficacy of assessment and treatment methods, the panel decided to focus on how each method affected clinical outcomes important to patients and society. Examples of such outcomes are symptoms, level of physical functioning, patient satisfaction, and morbidity and mortality (as complications of the assessment or treatment method). The panel dealt with costs, another outcome of interest to patients and society, as a separate issue. Cost was not considered when evaluating efficacy.

The panel used a standard methodology to identify and evaluate the best scientific evidence available on the efficacy of each assessment and treatment method, while focusing on clinical outcomes. This process included a systematic evaluation of each study's quality and its clinical applicability to patients with acute low back problems. The panel used this information to screen all articles, using minimum article selection criteria for efficacy. Articles meeting these minimum criteria were prioritized (giving priority to articles of higher quality and clinical applicability), and data from the higher priority articles were abstracted onto evidence tables.

The panel then reviewed the available data from both evidence tables and original articles to decide how much weight to give each study in developing the findings and recommendations statements for this guideline. The greatest weight was given to studies of high quality that evaluated adults with acute low back problems, although few such studies were found.

For most topics, the quality and clinical applicability of studies reviewed were limited. Inclusion and exclusion criteria for subjects were often either incompletely described or so broad that they allowed for wide variations in age, symptoms, symptom duration, examination findings, prior treatments, and other potentially confounding factors. Studies often inadequately described the baseline demographic and clinical characteristics of subjects. Many studies did not distinguish acute from chronic patients; others failed to either describe or control for factors known to cause significant variation in outcome (such as prior back surgery). Certain studies lacked appropriate statistical analysis or included too few subjects to attain adequate statistical power.

Evaluation of Potential Harms and Costs

Evaluating Harms. Since back problems are rarely life-threatening, the panel paid special attention to potential harms (side effects or complications) of assessment and treatment methods. Controlled trials evaluating treatment and assessment methods, however, seldom included enough subjects to detect rare but potentially serious complications. This information was found only in large case series or case reports. On the other hand, controlled trials of oral medications often included extensive information on side effects. Thus, accurate comparison of the relative risks of side effects and complications of

different assessment and treatment methods was not possible.

A lack of published evidence about harms related to specific treatment or assessment methods does not mean that potential harms do not exist. In many instances, the side effects and complications of assessment and treatment methods have never been extensively studied or comprehensively reported. In addition, articles evaluating newer treatment and assessment methods are often written by advocates of these methods, who may tend to deemphasize the harms.

The panel felt it was important for both clinicians and patients to have a sense of potential harms relative to the potential benefits of these methods. Therefore, the panel considered information about potential harms from a variety of sources, including case series, case reports, cross-sectional surveys, clinical trials, and in some instances studies of patients who did not have low back problems. Finally, if no specific information was available from any of these sources, the panel generally considered whether the method was invasive or carried the potential for an allergic reaction.

Evaluating Costs. Both clinicians and patients need to consider relative costs of assessment and treatment methods before making informed decisions about care. Costs vary greatly, however, and the cost data on assessment and treatment methods for low back problems are limited. The unit cost of a service may vary within and between geographical regions. The aggregate cost of services also varies depending on the frequency and duration of services for the individual patient. Although costs of various medical services have generally increased in recent years, they have done so at inconsistent rates. Given these variations, the panel decided to make broad statements about whether

methods appeared to be of low, moderate, or high cost, graded according to the following system (based on 1993 dollars):

1. Low cost: under $200.

2. Moderate cost: $200 to $1,000.

3. High cost: over $1,000.

This grading system provides no more than a rough comparison of costs, and the panel recognized that the divisions between cost categories are somewhat arbitrary. For example, some Americans may not consider a $199 expense that comes directly out of pocket to be "low cost."

Developing the Guideline Recommendations

To develop recommendations for each assessment and treatment method, the panel considered: (1) the quality and amount of evidence for efficacy, (2) the strength of the effect found for the method, (3) the consistency of findings between studies, (4) the clinical applicability of the evidence to adult patients with acute low back problems, and (5) any evidence on harms or costs. For each assessment and treatment method the panel then sought to answer the following questions:

1. What is the likelihood that this assessment or treatment method will:

   - Benefit the patient?

   - Harm the patient?

2. Does the likelihood and magnitude of potential benefit outweigh the likelihood and magnitude

of potential harm enough to justify the cost for this method?

The development of findings and recommendations statements required the collective judgment of the panel in interpreting the available evidence. The panel rated the amount and quality of evidence supporting each guideline statement using the scale in the Figure below.

Figure 1. Panel ratings of available evidence supporting guideline statements

A = **Strong** research-based evidence (multiple relevant and high-quality scientific studies).

B = **Moderate** research-based evidence (one relevant, high-quality scientific study or multiple adequate scientific studies*).

C = **Limited** research-based evidence (at least one adequate scientific study in patients with low back pain).

D = Panel interpretation of information that did **not** meet inclusion criteria as research-based evidence.

*Met minimal formal criteria for scientific methodology and relevance to population and specific method addressed in guideline statement.

This rating system (A, B, C, or D) is the basis for:

Recommendations for: If the available evidence indicates that potential benefits outweigh potential harms.

Options: If the available evidence of potential benefits is weak or equivocal (inconsistency in some studies) but potential harms and costs appear small.

Recommendations against: If the available evidence indicates either a lack of benefit or that potential harms and costs outweigh potential benefits.

The guideline's findings and recommendations statements therefore represent the panel's assessment of a method's potential to achieve the intended assessment or treatment goals, balanced against its potential harms and costs.

2. Initial Assessment Methods

Panel findings and recommendations:

- Information about the patient's age, the duration and description of symptoms, the impact of symptoms on activity, and the response to previous therapy are important in the care of back problems. (Strength of Evidence = B.)

- Inquiries about history of cancer, unexplained weight loss, immunosuppression, intravenous drug use, history of urinary infection, pain increased by rest, and presence of fever are recommended to elicit red flags for possible cancer or infection. Such inquiries are especially important in patients over age 50. (Strength of Evidence = B.)

- Inquiries about signs and symptoms of cauda equina syndrome, such as a bladder dysfunction and saddle anesthesia in addition to major limb motor weakness,

are recommended to elicit red flags for severe neurologic risk to the patient. (Strength of Evidence = C.)

- Inquiries about history of significant trauma relative to age (for example, a fall from height or motor vehicle accident in a young adult or a minor fall or heavy lift in a potentially osteoporotic or older patient) are recommended to avoid delays in diagnosing fracture. (Strength of Evidence = C.)

- Attention to psychological and socioeconomic problems in the individual's life is recommended since such nonphysical factors can complicate both assessment and treatment. (Strength of Evidence = C.)

- Use of instruments such as a pain drawing or visual analog scale is an option to augment the history. (Strength of Evidence = D.)

- Recording the results of straight leg raising (SLR) is recommended in the assessment of sciatica in young adults. In older patients with spinal stenosis, SLR may be normal. (Strength of Evidence = B.)

- A neurologic examination emphasizing ankle and knee reflexes, ankle and great toe dorsiflexion strength, and distribution of sensory complaints is recommended to document the presence of neurologic deficits. (Strength of Evidence = B.)

The initial assessment (Attachment A1) of a patient with activity intolerance due to acute low back symptoms consists of a focused medical history, a physical examination, and related decisions. A careful medical history and physical examination are critical. The primary purpose is to seek medical history responses or physical examination findings suggesting a serious underlying

condition such as fracture, tumor, infection, or cauda equina syndrome. These responses or findings are referred to as red flags. They alert clinicians to the possibility that low back symptoms may be related to a dangerous condition. However, serious conditions presenting as low back problems are relatively rare.

The initial assessment categorizes back symptoms without red flags as either primarily back (nonneurologic) or sciatic (neurologic) and defines the duration of these symptoms to guide both what type of special studies may be considered and when they should be considered. In the absence of red flags, special tests are not usually required in the first month of low back symptoms because most patients recover from their activity limitations within 1 month.

The initial assessment also provides an opportunity for the clinician to establish rapport with the patient, to find out patient expectations, and to become aware of potential psychological and socioeconomic factors that can alter response to care.

Assessment Literature Reviewed

Of the 214 articles screened for this topic, 34 met the article selection criteria for efficacy.[20-53]

The important points in these articles are well summarized in review articles by Deyo, Rainville, and Kent[54] and Waddell, Main, Morris, et al.[55] Both reviews elaborate on the reproducibility and accuracy of specific medical history findings (Table 1) and physical examination findings (Table 2) for assessing low back problems. Other articles not meeting selection criteria are cited where appropriate since they contain information used in formulating recommendations. [56-65]

Table 1. Estimated accuracy of medical history in diagnosis of spine diseases causing low back problems

References	Disease to be detected	Medical history red flags	True-positive rate (sensitivity)	True-negative rate (specificity)
Deyo and Diehl[26]	Cancer	Age ≥ 50	0.77	0.71
		Previous cancer history	0.31	0.98
		Unexplained weight loss	0.15	0.94
		Failure to improve with 1 month of therapy	0.31	0.90
		Bed rest no relief	>0.90	0.46
		Duration of pain >1 month	0.50	0.81

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		Age ≥50 or history of cancer or unexplained weight loss or failure of conservative therapy	1.00	0.60
Waldvogel and Vasey[64]	Spinal osteomyelitis	Intravenous drug abuse, UTI, or skin infection	0.40	NA
Unpublished data[a]	Compression fracture	Age ≥50	0.84	0.61
		Age ≥70	0.22	0.96
		Trauma	0.30	0.85
		Corticosteroid use	0.06	0.995
Deyo and Tsui-Wu[59]; Spangfort[53]	Herniated disc	Sciatica	0.95	0.88

[a] From 833 patients with back pain at a walk-in clinic as reported in Deyo, Rainville, and Kent[54] All received plain lumbar roentgenograms.

Turner, Ersek, Herron, et al.[86]	Spinal stenosis	Pseudoclaudication	0.60	NA
		Age ≥50	0.90[b]	0.70
Gran[50]	Ankylosing spondylitis	Positive responses 4 out of 5	0.23	0.82
		Age at onset ≤40	1.00	0.07
		Pain not relieved in supine position	0.80	0.49
		Morning back stiffness	0.64	0.59
		Duration of pain ≥3 months	0.71	0.54

[b] Author's estimate.

Table 2. Estimated accuracy of physical examination or lumbar disc herniation among patients with sciatica

References	Test	True-positive rate (sensitivity)	True-negative rate (specificity)	Comments
Hakelius and Hindmarsh [61]; Kosteljanetz, Espersen, Halaburt, et al.[37]	Ipsilateral SLR	0.80	0.40	Positive result: leg pain at <60°
Hakelius and Hindmarsh [61]; Spangfort[63]	Crossed SLR	0.25	0.90	Positive result: reproduction of contralateral pain
Hakelius and Hindmarsh [61]; Spangfort[63]	Ankle dorsiflexion weakness	0.35	0.70	HNP usually at L4-L5 (80%)
Hakelius and Hindmarsh [61];Kortelainen, Puranen, Koivisto, et al.[35]	Great toe extensor weakness	0.50	0.70	HNP usually at L5-S1 (60%) or L4-L5 (30%)

Hakelius and Hindmarsh[61]; Spangfort[63]	Impaired ankle reflex	0.50	0.60	HNP usually at L5-S1; absent reflex increases specificity
Kortelainen, Puranen, Koivisto, et al.[35]; Kosteljanetz, Espersen, Halaburt, et al.[37]	Sensory loss	0.50	0.50	Area of loss poor predictor of HNP level
Aronson and Dunsmore[58]	Patellar reflex	0.50	NA	For upper lumbar HNP only
Hakelius and Hindmarsh[61]	Ankle plantar flexion weakness	0.06	0.95	--
Hakelius and Hindmarsh[61]	Quadriceps weakness	<0.01	0.99	--

Note: Sensitivity and specificity were calculated by Deyo, Rainville, and Kent[54] Values represent rounded averages

where multiple references were available. All results are from surgical case series. HNP = herniated nucleus pulposous. SLR = straight leg raising.

Evidence on Efficacy of Assessment Methods

Medical History

A few key questions on the medical history can help ensure that a serious underlying condition, such as cancer[26] or spinal infection, will not be missed. These questions include: age, history of cancer, unexplained weight loss, immunosuppression, duration of symptoms, responsiveness to previous therapy, pain that is worse at rest, history of intravenous drug use, and urinary or other infection.

Symptoms of sciatica (leg pain) or neurogenic claudication (walking limitations due to leg pain) suggest possible neurologic involvement. Pain radiating below the knee is more likely to indicate a true radiculopathy than pain radiating only to the posterior thigh. A history of persistent numbness or weakness in the leg(s) further increases the likelihood of neurologic involvement. The articles indicate that cauda equina syndrome can be ruled out with a medical history that ascertains the absence of bladder dysfunction (usually urinary retention or overflow incontinence), saddle anesthesia, and unilateral or bilateral leg pain and weakness.

Patients' reports of symptoms and treatment outcomes may be influenced by psychological or socioeconomic factors. Several studies have reported a variety of such factors for patients with low back problems. These factors include work status, typical job tasks, educational level, pending litigation, worker's compensation or disability issues, failed previous treatments, substance abuse, and depression.[23, 38, 39, 41, 43, 50, 58]

Clinicians are urged by some authors to augment the medical history with pain drawings and visual analog pain rating scales to document the distribution of pain and intensity of symptoms (Attachment B).[40, 45, 46, 52, 53]

Physical Examination

The physical examination supplements the information obtained in the medical history in seeking an underlying serious condition or possible neurologic compromise. The basic elements of a physical examination are inspection, palpation, observation including range of motion testing, and a specialized neuromuscular evaluation. This evaluation emphasizes ankle and knee reflexes, ankle and great toe dorsiflexion strength, and distribution of sensory complaints. For patients presenting with acute low back problems and no limb complaints, a more elaborate neurologic evaluation is usually not necessary.

The physical examination is less useful than the history in searching for underlying serious conditions such as cancer, but may be helpful in detecting spinal infections. Fever, vertebral tenderness, and very limited spinal range of motion suggest the possibility of spinal infections, but these are also common findings in patients without infection. Otherwise, evaluation of spinal range of motion has been found to be of limited diagnostic value,[62] although some clinicians consider it helpful in planning and monitoring treatment.

Findings from both the history and physical examination provide useful information in the search for possible neurologic compromise. For example, sciatica has such a high true-positive rate for lumbar nerve root compression that its absence makes a clinically important lumbar disc herniation related to neural compression unlikely. In addition, leg pain usually overshadows back pain when

such a clinically significant radiculopathy is present. Finally, crossed straight leg raising is such a highly specific test that a positive finding makes neurologic compromise due to herniated lumbar disc very likely, but this is not a sensitive test since discomfort upon crossed straight leg raising may be absent in many patients with neurologic compression.[31, 34, 61, 63]

Deyo, Rainville, and Kent's summary[54] of available data suggests that in the primary care setting for patients with leg symptoms, the neurologic examination can safely be limited to a few tests. These are: (1) testing of dorsiflexion strength of the ankle and the great toe, with weakness suggesting L5 and some L4 root dysfunction; (2) testing of ankle reflexes to evaluate S1 root dysfunction; (3) testing of light touch sensation in the medial (L4), dorsal (L5), and lateral (S1) aspects of the foot; and (4) the straight leg raising (SLR) test.

This abbreviated neurologic examination of the lower extremities will allow detection of most clinically significant nerve root compromise due to L4-L5 or L5-S1 disc herniations, which together make up over 90 percent of all clinically significant radiculopathy due to lumbar disc herniations.[35, 37, 56, 61, 63] Although this limited examination might miss the much less common L2-L3 or L3-L4 disc herniations, these conditions are more difficult to diagnose on physical examination. Moreover, if such patients have not improved by 1 month, this guideline suggests a further diagnostic workup or consultation (Chapter 4), which may clarify the diagnosis. For over 95 percent of patients with acute low back problems, no special interventions or diagnostic tests would be required within the first month of symptoms.

Potential Harms and Costs of Assessment Methods

Potential harms and costs are considered low for both the medical history and the physical examination.

Summary of Findings

Positive answers to key medical history questions, in addition to positive findings on physical examination and/or simple lab tests, are red flags that suggest the possibility of a serious underlying condition as the cause of acute low back problems.

For cancer or infection, red flags are: history of cancer, unexplained weight loss, immunosuppression, urinary infection, intravenous drug use, prolonged use of corticosteroids, back pain not improved with rest, and age of patient over 50.

For spinal fracture, red flags are: history of significant trauma (for example, a fall from a height, motor vehicle accident, or direct blow to the back for a young adult, or a minor fall or heavy lift in a potentially osteoporotic or elderly individual), prolonged use of steroids, and age over 70.

For cauda equina syndrome or severe neurologic compromise, red flags are: medical history or physical examination findings of acute onset of urinary retention or overflow incontinence, loss of anal sphincter tone or fecal incontinence, saddle anesthesia (about the anus, perineum, and genitals), and global or progressive motor weakness in the lower limbs.

There are indications in the literature that psychological or socioeconomic factors may affect a patient's report of symptoms and response to treatment.

Simple laboratory tests, including complete blood count (CBC) and erythrocyte sedimentation rate (ESR), are sufficiently inexpensive and efficacious for use as initial tests when there is suspicion of back-related tumor or infection.

3. Clinical Care Methods

In the absence of red flags, treatment is similar for most patients with activity intolerance due to an acute episode of low back symptoms (Attachment A2). After assuring the patient that there is no hint of a dangerous problem and that a rapid recovery is expected, the goals are to provide accurate patient information about low back problems, to help provide comfort by means of symptom control methods, and to recommend activity modifications.

Patient Information

Patient Education About Low Back Symptoms

Panel findings and recommendations:

Patients with acute low back problems should be given accurate information about the following (Strength of Evidence = B):

- Expectations for both rapid recovery and recurrence of symptoms based on natural history of low back symptoms.
- Safe and effective methods of symptom control.
- Safe and reasonable activity modifications.
- Best means of limiting recurrent low back problems.

- The lack of need for special investigations unless red flags are present.

- Effectiveness and risks of commonly available diagnostic and further treatment measures to be considered should symptoms persist.

Patient education as defined here includes all forms of patient-oriented education about low back problems except for "back schools" (formally structured, classroom-style back education programs). Under this definition, patient education includes printed and audiovisual materials, information given by health care providers, and educational programs that are less formal than back schools.

Literature Reviewed. Of 14 articles screened for this topic, 2 met the criteria for review.[67,68] Other articles contained information used by the panel, but did not meet article selection criteria.[69-71]

Neither of the studies meeting the criteria focused solely on patients with acute low back problems. Both evaluated patients with low back problems of unspecified duration. Interventions evaluated included giving patients booklets on back pain[68] and holding a brief individual educational session during an emergency room visit or by phone after the visit. [67]

Evidence on Efficacy. Jones, Jones, and Katz[67] evaluated educational intervention for patients with low back problems who came to a hospital emergency department and were referred for followup care. Patients receiving an educational intervention in the emergency department and/or a followup phone call were more likely than control patients to schedule and keep their followup appointment.

Roland and Dixon[68] conducted a randomized controlled trial (RCT) in which patients presenting with low back problems were assigned either to a group receiving an educational booklet on back problems or to a control group receiving no educational materials. In the first 2 weeks after the intervention, no differences were found between the education and control groups in number of consultations for back pain. However, in the period from 2 weeks to 1 year after the intervention, significantly fewer patients in the group receiving the booklet consulted physicians for back pain.

The importance of providing information to the patient is indicated in a study by Deyo and Diehl.[70] Failure to receive an explanation of the problem was the most frequently cited source of patient dissatisfaction among 140 patients with low back problems. Patients who felt they did not receive an adequate explanation wanted more diagnostic tests, were less satisfied with their visit, and were less likely to want the same doctor again, compared with patients who reported an adequate explanation.

Thomas[71] randomly assigned patients with symptoms (including low back pain), but no definite diagnosis, to one of four consultations: either one of two positive consultations, with and without treatment, or one of two negative consultations, with and without treatment. In the positive consultations, patients were given a firm diagnosis and told confidently that they would be better in a few days. The negative consultations were devised so that no firm assurance was given. Two weeks later the difference in recovery was significant between the positive and negative groups, but not between the treated and untreated groups.

A study of patients visiting family physicians for common symptoms, including back or neck pain, found that

gaining patient agreement about the nature of the problem led to earlier resolution.[69]

Potential Harms and Costs. The potential risks, harms, and costs of educating patients are considered to below.

Summary of Findings. Evidence indicates that educating patients about back problems may reduce use of medical resources, decrease patient apprehension, and speed recovery.

Structured Patient Education: Back School

Panel findings and recommendations:

- In the workplace, back schools with worksite-specific education may be effective adjuncts to individual education efforts by the clinician in the treatment of patients with acute low back problems. (Strength of Evidence = C.)

- The efficacy of back schools in nonoccupational settings has yet to be demonstrated. (Strength of Evidence = C.)

"Back school" is defined here as a structured program of education about low back problems, usually in a group setting. The therapeutic objectives are to give the patient information on the anatomy and natural history of disorders of the back; to teach the principles underlying posture, daily activities, and sports; and thereby to increase functional work capacity.

Literature Reviewed. Of 35 articles screened for this topic, 15 reporting on 12 RCTs met criteria for review.[72-86]

Two meta-analyses regarding back schools were also examined.[87, 88] The panel used information from one other study that did not meet selection criteria.[89]

Evidence on Efficacy. One of the few studies demonstrating the efficacy of back school[72] was conducted in the medical department of a Swedish automotive assembly plant. The 217 subjects all had nonspecific low back pain for less than 3 months and were randomly assigned to one of three interventions: back school, combined physiotherapy exercise, or placebo shortwave diathermy. The back school intervention consisted of four 45-minute sessions in 2 weeks and included the following topics: anatomy and causes of low back problems, muscle function and posture, ergonomics, and advice on physical activity. Patients attending back school had a shorter duration of sick leave during the initial episode than the other two treatment groups, but at the 1-year followup neither the number nor the length of absences from work owing to recurrences differed among the three treatment groups.

A meta-analysis by Keijsers, Bouter, and Meertens [87] evaluated eight studies of back schools done in group settings.[72,73,76,79,81,85,86,89] These studies of back schools were compared in terms of program duration and content, patient selection criteria, number of patients, interventions, and outcome measures used. All eight studies were found to have major methodological problems. The authors found that although there was insufficient evidence to form a strong and valid judgment on the efficacy of back schools, the available evidence suggested that back schools are at most marginally effective.

Another meta-analysis by Linton and Kamwendo[88] reviewed the scientific literature on back schools and reported some positive effects in studies of patients with

acute back pain. However, the authors found that most studies of back schools lacked adequate control groups and that the evidence on efficacy is inconclusive.

Potential Harms and Costs. The potential risks and harms of back schools are considered low. Costs are variable, depending on the number of sessions and the setting, and range from moderately inexpensive to expensive.

Summary of Findings. Available data on formal patient education programs, or back schools, vary in terms of program quality, length, content, costs, and outcomes. Only one study of a structured low back education program, performed in industry, was found to have a positive short-term impact on acute low back problems although no effect was seen at 1-year followup.[72] In summary, the published evidence on back school as a treatment for acute low back problems is limited in quantity and the results are contradictory.

Symptom Control Methods

Symptom control methods focus initially on providing comfort to keep the patient as active as possible while awaiting spontaneous recovery and, later in treatment, on aiding the activation needed to overcome a specific activity intolerance. The methods traditionally include oral medications, such as acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs), as well as physical treatments. They also include therapeutic injections. Proving the efficacy of these methods to relieve acute low back symptoms is difficult due to the rapid rate of spontaneous recovery. The use of symptom control methods known to have less risk of harm than methods with proven efficacy may thus be warranted if such methods are inexpensive and

allow an individual to remain active or build activity tolerance through exercise.

Symptom Control: Medications

Acetaminophen and NSAIDs

Panel findings and recommendations:

- Acetaminophen is reasonably safe and is acceptable for treating patients with acute low back problems. (Strength of Evidence = C.)

- Nonsteroidal anti-inflammatory drugs (NSAIDs), including aspirin, are acceptable for treating patients with acute low back problems. (Strength of Evidence = B.)

- NSAIDs have a number of potential side effects. The most frequent complication is gastrointestinal irritation. The decision to use these medications can be guided by comorbidity, side effects, cost, and patient and provider preference. (Strength of Evidence = C.)

- Phenylbutazone is not recommended, based on an increased risk for bone marrow suppression. (Strength of Evidence = C.)

Acetaminophen, a nonnarcotic analgesic, has commonly been regarded as having an analgesic effect, but little or no known anti-inflammatory mechanism. The therapeutic objective for its use in acute low back problems is pain relief.

NSAIDs are a class of medications, including aspirin, ibuprofen, indomethacin, phenylbutazone, and a variety of other drugs. They have anti-inflammatory and analgesic

properties as well as being prostaglandin inhibitors. The therapeutic objective of NSAIDs in treating acute low back problems is to decrease pain, presumably by reducing inflammation and promoting healing.

Literature Reviewed. Of 50 articles screened for this topic, 4 RCTs met the review criteria for adequate evidence about efficacy.[85,90-92] Other articles did not meet the criteria, but contained information used by the panel.[93-103]

Evidence on Efficacy. The four RCTs that met review criteria for this topic were all double-blind studies comparing NSAIDs with a placebo in treating patients with low back problems. No studies were found that compared acetaminophen to placebo in treatment of patients with low back pain.

Two studies compared a single NSAID to a placebo: Amlie, Weber, and Holme[90] evaluated piroxicam. Postacchini, Facchini, and Palieri[85] evaluated diclofenac. The study by Berry, Bloom, Hamilton, et al.[92] had three treatment groups evaluating either one of two NSAIDs (diflunisal or naproxen sodium) or a placebo. The study by Basmajian[91] compared four treatment groups receiving an NSAID alone (diflunisal), a muscle relaxant alone (cyclobenzaprine), the two in combination, or a placebo.

Three of the studies evaluated patients with acute low back symptoms of less than 3 months' duration.[85,90,91] Berry, Bloom, Hamilton, et al.[92] evaluated patients with chronic low back pain.

Three studies found NSAIDs superior to a placebo for pain relief in the short term: from 1 week to 2 months of symptom duration.[85,90,92] The remaining study found no significant difference between NSAID and placebo in terms of pain improvement scores.[91]

Although there were no RCTs comparing acetaminophen to placebo for patients with low back pain, one nonplacebo-controlled RCT found an NSAID (diflunisal) superior to paracetamol (which is similar to acetaminophen) in producing pain relief for patients with chronic low back pain.[97] In addition, the literature on acetaminophen does show it to be more effective than placebo in studies of patients with nonback-related pain.[98,102]

Several RCTs comparing efficacy of different NSAIDs in the same study have found no NSAID to be consistently more effective than the others.[96,101,102] However, these studies also suggest that individual patients report better pain relief from some NSAIDs compared with others. For this reason, Brooks and Day[93] suggest that patients change to a different NSAID if no relief is reported after a 2-week trial.

Potential Harms and Costs. The risks from the use of acetaminophen at usual doses are low.[95] However, high doses of acetaminophen can lead to liver damage, and massive single doses sometimes lead to fatal hepatic necrosis. Compared with NSAIDs, acetaminophen has a minimal effect on platelets and few gastrointestinal side effects since it is not a mucosal irritant. Acetaminophen is inexpensive. The expense of treatment with NSAIDs varies greatly, depending on the medication used and the length of treatment.

Potential complications of NSAIDs have been extensively studied.[93,95] These include gastritis and other gastrointestinal complaints, including bleeding in 20 to 30 percent of those patients with active peptic ulcer problems. The degree of gastrointestinal side effects from NSAIDs appears to be dose related, but side effects can occur with one tablet. Ingestion of NSAIDs with meals or in combination with antacids has not been proven effective in

reducing these gastrointestinal side effects. However, one medication (misoprostol), when taken with NSAIDs, has been shown to reduce NSAID-induced gastric erosion and the risk for gastroduodenal ulcers.[99,100]

NSAIDs interfere with platelet adhesion and renal sodium metabolism. Their use in patients with a bleeding diathesis is considered contraindicated. They can be used in the presence of hypertension, renal disease, and edematous states, but only if great caution is exercised.[93] For these reasons, some experts caution that routine blood tests (such as CBC and serum chemistry screen) be done before treatment for older patients or those with vascular disease. These tests are also recommended if there is any suspicion of complications for those patients on prolonged NSAID therapy.[95]

Phenylbutazone has been associated with bone marrow suppression (aplastic anemia and agranulocytosis). Indomethacin has a higher reported incidence of gastrointestinal side effects than other NSAIDs. Otherwise, there is no significant demonstrated difference between remaining NSAID preparations in terms of the prevalence or severity of complications. [95]

Summary of Findings. There is fair to good evidence that NSAIDs are effective for reducing pain in patients with acute low back problems. Although no studies were found comparing acetaminophen to placebo in patients with back pain, there is evidence that acetaminophen is comparable in efficacy to NSAIDs for treating back problems and with fewer side effects. In studies of patients with nonback pain, no consistent difference in symptom relief has been demonstrated between acetaminophen and any available NSAID (including aspirin). Both NSAIDs and acetaminophen have been found to be generally adequate to achieve pain relief.

Muscle Relaxants

Panel findings and recommendations:

- Muscle relaxants are an option in the treatment of patients with acute low back problems. While probably more effective than placebo, muscle relaxants have not been shown to be more effective than NSAIDs. (Strength of Evidence = C.)

- No additional benefit is gained by using muscle relaxants in combination with NSAIDs over using NSAIDs alone. (Strength of Evidence = C.)

- Muscle relaxants have potential side effects, including drowsiness in up to 30 percent of patients. When considering the optional use of muscle relaxants, the clinician should balance the potential for drowsiness against a patient's intolerance of other agents. (Strength of Evidence = C.)

Muscle relaxants are commonly used for the treatment of low back problems. Pharmacologically, these are usually benzodiazepines, other sedative medications, or antihistamine derivatives. The therapeutic objective of muscle relaxants is to reduce low back pain by relieving muscle spasm. However, the concept of skeletal muscle spasm is not universally accepted as a cause of symptoms, and the most commonly used muscle relaxants have no peripheral effect on muscle spasm.

Literature Reviewed. Of 42 articles screened for this topic, 12 RCTs met review criteria for adequate evidence about efficacy.[91,104-114]

Evidence on Efficacy. Three studies evaluating patients with low back problems either did not specify duration of

symptoms or included a mix of patients with acute and chronic problems.[104,113,114] The remaining nine studies evaluated only patients with acute low back problems.

Of the articles that met review criteria, 9 evaluated a muscle relaxant compared with a placebo.[91,104,105,108-113] Two studies compared two different muscle relaxants.[107,114] Some of the studies also compared a muscle relaxant to another medication, including a barbiturate;[110,111] an NSAID;[91,106] and acetaminophen.[91]

Of the nine studies comparing muscle relaxants with placebos, seven had results favoring the muscle relaxant.[104,105,108-111,113] Two showed no difference in outcomes between muscle relaxant and placebo.[91,112] In most studies, the positive effect for muscle relaxants was short-lived, lasting no more than 4 to 7 days, with no significant difference from placebo seen after this time.

Panel methodologists did a meta-analysis of the 12 studies that met panel review criteria. The studies were assessed for quality without knowledge of the results. There was one excellent study,[107] three good studies,[105,109,114] and eight fair studies.[91,104,106,108,110-113]

Each study was examined for outcome measures such as pain, functional capacity, or a global measure of improvement. When meta-analytically combined, the studies showed a trend toward greater improvement in the patients treated with muscle relaxants, but did not reach statistical significance. Even if the findings had reached significance, statistical combinations of such study results should be interpreted with caution. The conclusion of the meta-analysis was that muscle relaxants are probably, but not certainly, more effective than placebos in decreasing symptoms of acute low back problems. However, there was not enough evidence to determine whether muscle relaxants

are more or less effective than NSAIDs for reducing symptoms or whether the addition of a muscle relaxant adds to the efficacy of an NSAID.

Potential Harms and Costs. Potential complications of muscle relaxants include drowsiness and dizziness, reported to be up to 30 percent higher in patients taking muscle relaxants compared with patients taking placebos.[91,104,105,108-113] The cost of muscle relaxants is considered low to moderate.

Summary of Findings. There is moderate research evidence that muscle relaxants are more effective than placebo, but no evidence that they are better than NSAIDs, in relieving symptoms of acute low back problems. These medications have substantial potential side effects, especially a high incidence of drowsiness.

Opioid Analgesics

Panel findings and recommendations:

- When used only for a time-limited course, opioid analgesics are an option in the management of patients with acute low back problems. The decision to use opioids should be guided by consideration of their potential complications relative to other options. (Strength of Evidence = C.)

- Opioids appear to be no more effective in relieving low back symptoms than safer analgesics, such as acetaminophen or aspirin or other NSAIDs. (Strength of Evidence = C.)

- Clinicians should be aware of the side effects of opioids, such as decreased reaction time, clouded judgment, and drowsiness, which lead to early discontinuation by as

many as 35 percent of patients. (Strength of Evidence = C.)

- Patients should be warned about potential physical dependence and the danger associated with the use of opioids while operating heavy equipment or driving. (Strength of Evidence = C.)

Oral opioid analgesics commonly given to patients with acute low back problems include morphine derivatives (opioids) and synthetic opioids. The therapeutic objective in treating low back problems is temporary pain relief.

Literature Reviewed. No RCTs were found that compared opioid analgesics (either alone or in combination with other drugs) to a placebo. Therefore, three studies were evaluated that compared opioid analgesics to other medications,[115-117] recognizing that results of the evaluation would not entirely answer the question of whether opioids are any better than placebo for back symptoms. Another article[118] contained information used by the panel.

Evidence on Efficacy. All three studies evaluated patients with acute low back problems, but with a mixed group of medications. Two reports compared acetaminophen with codeine to diflunisal (an NSAID) with patients treated for 1 and 2 weeks, respectively.[115,116] The third study compared three groups, one group receiving codeine, one oxycodone plus aspirin, and one acetaminophen.[117]

At the conclusion of treatment, Muncie, King, and DeForge[116] and Brown, Bodison, Dixon, et al.[115] found no significant differences between groups in terms of pain relief or functional improvement.

Wiesel, Cuckler, Deluca, et al.,[117] who evaluated a population of military recruits with acute low back pain,

found no difference between the three medication groups in amount of time before patients returned to full activities. Pain relief was claimed to be superior in groups receiving opioid analgesics compared with acetaminophen, with the greatest effect seen in the first 3 days of treatment. No statistics were reported to support the claim.

Potential Harms and Costs. Side effects reported by subjects receiving acetaminophen with codeine included dizziness, fatigue, inability to concentrate, impaired vision, drowsiness, nausea, and constipation.[115,116] In one study, 35 percent of subjects receiving acetaminophen with codeine had to discontinue the medication because of intolerable side effects.[116] Prolonged use of opioid analgesics is associated with the development of tolerance and physical dependence. A risk of developing physical dependence with short-term use of opioids has also been reported.[118]

The expense of treatment with these medications varies greatly, depending on the medication used and the length of treatment.

Summary of Findings. There are no well-designed controlled studies that evaluate the use of opioid analgesics compared with no treatment in patients with acute low back problems. The studies reviewed found that patients taking opioid analgesics did not return to full activity sooner than patients taking NSAIDs or acetaminophen. In addition, two studies found no difference in pain relief between NSAIDs and opioids. Finally, side effects of opioid analgesics were found to be substantial, including the risk for physical dependence. These side effects are an important concern in conditions that can become chronic, such as low back problems.

Oral Steroids

Panel findings and recommendations:

- Oral steroids are not recommended for the treatment of acute low back problems. (Strength of Evidence = C.)

- A potential for severe side effects is associated with the extended use of oral steroids or the short-term use of steroids in high doses. (Strength of Evidence = D.)

Oral steroids (corticosteroids) are used by some clinicians in the treatment of patients with acute low back problems. The therapeutic objective is to reduce inflammation in an attempt to promote healing and reduce pain.

Literature Reviewed. Of six articles screened for this topic, the only one meeting criteria for review was Haimovic and Beresford.[119] Two other articles also contained information used by the panel.[120,121]

Evidence on Efficacy. Haimovic and Beresford,[119] in a double-blind RCT, evaluated patients with low back pain who had findings of a single nerve root irritation (symptom duration of patients not specified). Patients were randomly assigned to receive a 1-week course of either an oral dexamethasone or a placebo. On followup at the end of treatment and at 1 year, no significant differences were found between the two groups in terms of pain relief.

Potential Harms and Costs. The incidence of side effects associated with steroids correlates with the potency of the drug, dosage, and duration of administration. Well-recognized complications from the prolonged use of oral steroids include suppression of pituitary-adrenal function, fluid and electrolyte disturbance, hyperglycemia,

demineralization of bone, and immunosuppression (with increased susceptibility to infection). While many of these effects can be reduced or eliminated with alternate-day therapy, even short-term daily use of high-dose steroids can contribute to posterior subcapsular cataract formation, myopathy, central nervous system disturbance, and avascular necrosis of bone, especially of the femoral head.[120,121]

The expense of treatment varies greatly, depending on the medication used and the length of treatment.

Summary of Findings. The limited available research evidence indicates that oral steroids do not appear to be an effective treatment for patients with acute low back problems. Serious potential complications are associated with long-term use, but potential complications appear minimal with short-term use.

Colchicine

Panel findings and recommendations:

Based on conflicting evidence of effectiveness as well as the potential for serious side effects, colchicine is not recommended for treating patients with acute low back problems. (Strength of Evidence = B.)

Colchicine has been used primarily to treat acute attacks of gouty arthritis and can be administered intravenously or orally. The therapeutic objective of using the drug in patients with acute low back problems is to reduce inflammation and thereby reduce pain.

Literature Reviewed. Of 13 articles screened, 3 RCTs met criteria for review.[122-124] Schnebel and Simmons[123] evaluated only patients with acute low back problems of less than 3

months' duration. Meek, Giudice, McFadden, et al.[122] evaluated patients with symptoms of more than 2 months. Simmons, Harris, Koulisis, et al.[124] evaluated those with symptoms lasting up to 6 months.

Evidence on Efficacy. Schnebel and Simmons[123] found no statistically significant difference between oral colchicine and a placebo, although the oral colchicine group did have significantly more diarrhea and vomiting than the placebo group. Simmons, Harris, Koulisis, et al.,[124] who compared groups receiving either intravenous colchicine or intravenous saline, found significantly improved pain ratings for the colchicine group, but pain relief was short-lived (lasting from 1 hour to 2 days). Also, two patients in the colchicine group developed complications (diarrhea and a local inflammatory response). Meek, Giudice, McFadden, et al.,[122] who evaluated for 1 month a group receiving one dose of intravenous colchicine followed by oral colchicine, compared with a group receiving placebo, found significantly greater pain relief in the colchicine group.

Potential Harms and Costs. Potential complications from the use of colchicine are gastrointestinal irritation, skin problems, severe chemical cellulitis from intravenous infiltration, and bone marrow suppression with agranulocytosis.[124] The expense of treatment with colchicine varies greatly, depending on whether oral or intravenous administration is used and on length of treatment.

Summary of Findings. Research evidence is limited and conflicting on whether colchicine, given either orally or intravenously, is an effective treatment for patients with acute low back problems. Serious potential side effects have been reported with use of this medication.

Antidepressant Medications

Panel findings and recommendations:

Antidepressant medications are not recommended for the treatment of acute low back problems. (Strength of Evidence = C.)

Antidepressant medications have been widely used for both depressed and nondepressed patients with chronic low back problems. The extent to which these medications are used in treating patients with acute low back problems is unknown. Some researchers have hypothesized that the medications may possibly have a pain-relieving effect in addition to antidepressant properties. If so, the medications could help some patients who have chronic pain whether or not the patients are also depressed. The therapeutic objective of using antidepressant medications for low back problems is to reduce pain.

Literature Reviewed. Of 18 articles screened, 3 RCTs met review criteria.[125-127] Other articles also contained information used by the panel.[128,129]

Evidence on Efficacy. No studies were found evaluating the efficacy of antidepressant medications for treatment of acute low back problems. The three studies reviewed all compared an antidepressant medication to a placebo in a double-blind fashion in patients with chronic, not acute, low back pain. These studies all randomized patients to receive either a pharmacologically inert placebo or an antidepressant medication. Alcoff, Jones, Rust, et al.[125] used imipramine, as did Jenkins, Ebbutt, and Evans.[127] Goodkin, Gullion, and Agras[126] used trazodone. The studies found no significant differences between groups receiving antidepressant and placebo in terms of pain reduction, functional limitations, depression, or the use of opioids. All

three studies had methodological flaws, including small sample sizes, lack of power calculations, and incomplete description of followup.

Potential Harms and Costs. Antidepressant medications can produce a variety of side effects including dry mouth, drowsiness, constipation, urinary retention, orthostatic hypotension, and mania.[128,129]

The cost of treatment with antidepressant medications can vary from low to high depending on the medication used, dose, and length of treatment.

Summary of Findings. No studies were found that evaluated the efficacy of antidepressant medications for treatment of acute low back problems. The studies reviewed all evaluated patients with chronic low back problems. They found no significant differences between antidepressants and placebo on any outcome measured. Numerous reported side effects are associated with antidepressant medications, but the potential for serious side effects is small in otherwise healthy adults.

Symptom Control: Physical Treatments

Spinal Manipulation

Panel findings and recommendations:

- Manipulation can be helpful for patients with acute low back problems without radiculopathy when used within the first month of symptoms. (Strength of Evidence = B.)

- When findings suggest progressive or severe neurologic deficits, an appropriate diagnostic assessment to rule out serious neurologic conditions is indicated before beginning manipulation therapy. (Strength of Evidence = D.)

- There is insufficient evidence to recommend manipulation for patients with radiculopathy. (Strength of Evidence = C.)

- A trial of manipulation in patients without radiculopathy with symptoms longer than a month is probably safe, but efficacy is unproven. (Strength of Evidence = C.)

- If manipulation has not resulted in symptomatic improvement that allows increased function after 1 month of treatment, manipulation therapy should be stopped and the patient reevaluated. (Strength of Evidence = D.)

Spinal manipulation includes many different techniques. For this guideline, manipulation is defined as manual therapy in which loads are applied to the spine using short or long lever methods. The selected joint is moved to its end range of voluntary motion, followed by application of an impulse loading. The therapeutic objectives of manipulation include symptomatic relief and functional improvement.

Literature Reviewed. Of the 112 articles screened for this topic, 13 reporting on 12 RCTs met criteria for review.[72,85,130-140]

The panel also considered recent meta-analyses and cost analyses.[141-144] In addition, the panel used information from articles that did not meet selection criteria.[145-149]

Evidence on Efficacy. The meta-analysis by Shekelle, Adams, Chassin, et al.[144] was based on 29 controlled trials of manipulation for low back problems. Nine of the studies used in the meta-analysis focused on patients with acute low back problems and tested the effect of manipulation

against sham manipulation[136] or various other conservative treatments.[72,132,135,137,138,140,145,149]

Of those RCTs that evaluated manipulation in patients with acute low back pain, the two highest quality studies used similar research designs.[136,137] Both these studies randomly assigned patients to either a group receiving manipulation or a nontreatment control group, with patients stratified by whether symptoms had lasted less than 14 days, 14 to 28 days, or over 28 days in one study.[137] For patients with 14 to 28 days of symptoms, both studies found the manipulation groups had statistically significant improvement in pain relief and functioning compared with the control groups. However, this effect was only seen within the first 2 weeks after starting treatment. For patients with symptoms of less than 14 days or over 28 days, no differences in improvement were found between the manipulation and control groups for any followup times.

A meta-analysis of the remaining seven studies also showed statistically significant short-term effects of manipulation in hastening recovery from low back problems.[144] Another meta-analysis, based on 23 randomized controlled trials of manipulation or mobilization, came to a similar conclusion.[sup141 This analysis indicated that, in patients with acute low back problems without radiculopathy, manipulation reduces pain and has positive short-term impact on daily functioning. Most studies have concentrated upon outcomes assessed within the first month of care.

The meta-analysis by Shekelle, Adams, Chassin, et al.[144] analyzed, in addition, studies of spinal manipulation in patient groups who had predominantly chronic low back problems, a mix of acute and chronic low back problems, or pain of undetermined duration. Studies of manipulation in

these groups had conflicting results concerning the efficacy of manipulation.

Shekelle, Adams, Chassin, et al.[144] also analyzed three studies on the use of spinal manipulation for patients with low back problems who had radiculopathy, but concluded that the evidence was insufficient to demonstrate efficacy.[131,146,148]

Potential Harms and Costs. Shekelle, Adams, Chassin, et al.[144] described published case reports of patients presenting with sciatica who had increasing neurologic deterioration following manipulation, but estimated that the risk of serious complications from lumbar spinal manipulation is small and may vary with the clinical condition with which the patient presents. No systematic report of frequency of complications from spinal manipulative therapy has been published. Mandell, Lipton, Bernstein, et al.[147] listed autonomic disturbances such as faintness, perspiration, and hyperventilation as common short- term reactions to manipulation. The total cost of manipulative therapy is determined by the frequency and duration of care.

Summary of Findings. The evidence for effectiveness of manipulation varies depending on the duration and nature of the patient's presenting symptoms. For patients with acute low back symptoms without radiculopathy, the scientific evidence suggests spinal manipulation is effective in reducing pain and perhaps speeding recovery within the first month of symptoms. For patients whose low back problems persist beyond 1 month, the scientific evidence on effectiveness of manipulation was found to be inconclusive. For patients with radiculopathy, the scientific evidence was also inconclusive about either the effectiveness or the potential harms of manipulation. Finally, the panel offered the opinion that, for patients with acute low back problems and findings of possible progressive or severe neurologic

deficits, assessment to rule out serious neurologic conditions is indicated before initiating manipulation therapy.

Physical Agents and Modalities

Panel findings and recommendations:

The use of physical agents and modalities in the treatment of acute low back problems is of insufficiently proven benefit to justify their cost. As an option, patients may be taught self- application of heat or cold to the back at home. (Strength of Evidence = C.)

Physical agents and modalities include ice, heat (including diathermy), massage, ultrasound, cutaneous laser treatment, and electrical stimulation (not transcutaneous electrical nerve stimulation or TENS). The therapeutic objective of physical agents and modalities is to provide symptomatic relief and, for some modalities, to reduce inflammation, "muscular symptoms," or joint stiffness.

Literature Reviewed. Of 25 articles screened for this topic, 10 reporting on 8 RCTs met criteria for review.[85,133,140,150-156]

Evidence on Efficacy. Many studies compared different combinations of physical agents and modalities, making it difficult to evaluate effectiveness of specific modalities. Only two studies evaluated physical agents and modalities in patients with acute low back pain.[85,140] Neither found significant differences in self-rated pain relief or other outcome measures between patient groups receiving physical agents and modalities (including diathermy, ultrasound, flexion/extension exercises, massage, and electrotherapy) and groups receiving a placebo.

The other studies reported on groups of either chronic or a mix of acute and chronic low back pain patients. Three

studies found no significant differences in patient-reported outcome measures between treatments (including cutaneous laser, diathermy, electrotherapy, exercise, heat, massage, and ultrasound) and a placebo.[133,150-153] Manniche, Hesselsoe, Bentzen, et al.[155] found intensive back-strengthening exercises superior to physical agents and modalities on patient-rated outcome measures, but the group receiving physical agents/modality treatment was not compared with a control group receiving no intervention. Melzack, Vetere, and Finch[156] found that a group receiving TENS therapy had greater pain relief than a group receiving massage therapy. Again, treatments were not compared with a no-intervention control. Linton, Bradley, Jensen, et al.[154] found that a group given a combination of physical agents and modalities, ergonomic education, and behavioral therapy had significantly better outcomes than a control group receiving no intervention, but the effect of physical agents and modalities could not be determined.

Potential Harms and Costs. Risks from potential complications of physical agents and modalities are believed to be small. A possible exception is in pregnant patients, for whom ultrasound and diathermy are not recommended because of theoretical risks to the fetus.

The costs of individual treatment sessions using physical agents and modalities are variable, determined by the number of modalities used, the length of treatment, and the number of treatment visits.

Summary of Findings. No well-designed controlled trials support the use of physical agents and modalities as treatments for acute low back problems. However, some patients with acute low back problems appear to have temporary symptomatic relief with physical agents and modalities. Therefore, self-administered home programs for

modalities involving heat or cold are considered a treatment option.

Transcutaneous Electrical Nerve Stimulation

Panel findings and recommendations:

Transcutaneous electrical nerve stimulation (TENS) is not recommended in the treatment of patients with acute low back problems. (Strength of Evidence = C.)

A TENS unit is a small battery-operated device worn by the patient. It provides continuous pulses of electricity by way of surface electrodes. Presumably, TENS produces a counter-stimulation of the nervous system, which can modify pain perception. The therapeutic objective of TENS in patients with low back problems is to provide symptomatic pain relief.

Literature Reviewed. Of 34 articles screened for this topic, 9 articles reporting on 8 RCTs met criteria for review.[156-164] Only one study evaluated patients with acute low back pain.[160]

Evidence on Efficacy. Hackett, Seddon, and Kaminski[160] evaluated a treatment called "electroacupuncture," which consisted of low-amplitude pulsed electrical current administered by way of surface electrodes rather than by needles. The panel considered this a variation of TENS rather than a type of acupuncture since no needling was involved. For the study, 37 patients with low back pain of less than 3 days' duration were randomly assigned to groups receiving either two 15-minute treatments of electroacupuncture and placebo tablets or paracetamol tablets and placebo electroacupuncture with no current applied. There was no difference in results at 1 and 2 weeks. By the sixth week after the initial treatment, patients who

had electroacupuncture reported significantly less pain, measured on a visual analog pain-rating scale, compared with those who took paracetamol.

The other studies reviewed focused on patients with chronic low back pain or other types of chronic pain or on a mixture of acute and chronic low back pain patients. The largest randomized study of TENS was carefully blinded and found no benefit for TENS over sham TENS in patients with chronic low back problems.[157] The remaining studies were of variable quality and were inconclusive regarding efficacy of TENS for relieving chronic pain.

Potential Harms and Costs. The risks of TENS are considered low. The cost of this treatment is considered low to moderate (depending upon whether the equipment is rented or owned by the patient).

Summary of Findings. There is inconclusive evidence of the efficacy of TENS in patients with acute low back problems. Only one published study addresses this issue, and its findings are considered weak.

Shoe Insoles and Shoe Lifts

Panel findings and recommendations:

- Shoe insoles may be effective for patients with acute low back problems who stand for prolonged periods of time. Given the low cost and low potential for harms, shoe insoles are a treatment option. (Strength of Evidence = C.)

- Shoe lifts are not recommended for treatment of acute low back problems when lower limb length difference is <=2 cm. (Strength of Evidence = D.)

Shoe insoles (or inserts) are devices placed inside shoes that may vary from over-the-counter foam or rubber inserts to custom-made orthotics. The therapeutic objective of shoe inserts is the reduction of back pain.

Shoe lifts (or raises) are additions made to the heel or sole of a shoe to increase its height. The therapeutic objective of shoe lifts is to compensate for lower limb length inequality and thereby reduce back pain.

Literature Reviewed. Of seven articles reviewed for this topic, only one was an RCT that met criteria for review.[165] Other articles contained information used by the panel, but did not meet article selection criteria.[166-168]

Evidence on Efficacy. Basford and Smith[165] used a randomized crossover design to evaluate the use of shoe insoles compared with no insoles in adults with mild back pain who spent at least 75 percent of each workday standing. Of 39 subjects studied, 44 percent reported reduced back pain when using the insoles, 3 percent reported increased back pain, and 51 percent reported no difference. Of the subjects who reported no improvement, many stated that their shoes were too tight to allow insoles to be added comfortably.

There were no controlled trials that evaluated shoe lifts in patients with either acute or chronic low back problems. The extent to which leg length inequality might be associated with low back problems has not been established. Lower limb length differences of up to 2 cm are frequently seen in subjects with no history of low back problems.[167,168] One study evaluated aircraft industry workers and found no correlation between a 2-cm limb length inequality and either previous back problems or later reports of back complaints.[166]

Potential Harms and Costs. Shoe insoles and shoe lifts are low-risk treatments; their cost varies from low (for ready-made items) to moderate (for custom-made orthotics).

Summary of Findings. Limited evidence (one crossover study) indicates that shoe insoles may reduce back pain in some individuals with mild back complaints. There is no evidence they provide any long-term benefit. The extent to which leg length inequality might be associated with acute low back problems has not been established, although differences of less than 2 cm are unlikely to be problematic.

Lumbar Corsets and Back Belts

Panel findings and recommendations:

- Lumbar corsets and support belts have not been proven beneficial for treating patients with acute low back problems. (Strength of Evidence = D.)

- Lumbar corsets, used preventively, may reduce time lost from work due to low back problems in individuals required to do frequent lifting at work. (Strength of Evidence = C.)

Lumbar support devices for low back problems include lumbar corsets and support belts, back braces and molded jackets, and back rests for chairs and car seats. The panel decided to evaluate only lumbar corsets and support belts for this guideline. Among theories on why lumbar corsets and support belts might help treat or prevent low back problems are that they compress the abdomen (causing increased intra-abdominal pressure, which unloads the vertebral column) and/or that they act as a mechanical reminder to decrease bending. Therapeutic objectives of lumbar supports are to control pain and/or protect against injury.

Literature Reviewed. Of 31 articles screened, 3 RCTs about lumbar corsets and support belts met review criteria for adequate evidence about efficacy.[131,169,170] Another article contained information used by the panel, but did not meet selection criteria.[171] None of these studies evaluated only patients with acute low back problems. One evaluated only chronic low back pain patients.[171] One evaluated a mixed group of acute and chronic low back pain patients.[131] The other two studies evaluated the prevention of low back problems in workers doing frequent lifting tasks.[169,170]

Evidence on Efficacy. Coxhead, Meade, Inskip, et al.[131] compared lumbar corset use to traction, exercise, and manipulation but included other interventions, making the direct effect of corset use difficult to determine.

Million, Haavik Nilsen, Jayson, et al.[171] compared the use of two types of lumbar corsets, one with and one without a lumbar support, in patients with chronic low back problems (all with symptoms longer than 6 months). This study was an RCT, but had too few subjects to meet review criteria. Although this study found a considerable and significant improvement in symptoms in the group wearing corsets with a lumbar support, no control group was used in the study to ascertain the effect of corset use as compared with no corset use.

Walsh and Schwartz,[170] in an RCT, evaluated 90 grocery warehouse workers not currently receiving treatment for low back problems. Subjects were randomly assigned to three groups. One group received a custom-molded lumbar corset plus a 1-hour training program on proper lifting, one the training program alone, and one no intervention. During the 6-month study period, no significant differences were reported between groups in back injury rates or in time lost from work due to back problems. However, the group assigned to lumbar corsets plus training showed

significantly less time loss from work due to back symptoms during the 6 months of the study when compared with the prior 6-month period. No similar significant effect was found for the other two groups.

Reddell, Congleton, Huchingson, et al.,[169] in an RCT, evaluated 642 airline baggage handlers randomly assigned to use of a lumbar weightlifting belt, with and without a supplemental training class, or to the training class alone, or to no intervention. The 1-hour training course included instruction on proper lifting techniques, and employees were given stretching exercises to be done before each flight. Over an 8-month period, no significant differences were found between groups studied in back injury claims or in days lost from work. However, the validity of these results is questionable since 58 percent of workers assigned to wear weightlifting belts stopped using them before the end of the study period.

Potential Harms and Costs. Some authors suggest that the prolonged use of lumbar corsets and support belts may lead to a decrease in strength of abdominal and back muscles, but no clear evidence of this was found in patients with low back problems. Walsh and Schwartz[170] found that no such weakness occurred in workers who wore lumbar corsets for 6 months as a preventive measure. In the study by Reddell, Congleton, Huchingson, et al.,[169] the majority of workers who stopped wearing weightlifting belts complained that the belts were too hot and/or too uncomfortable.

The cost of lumbar corsets and support belts varies from low to moderately expensive.

Summary of Findings. There is no evidence that lumbar corsets or support belts are effective for treating acute low back problems and conflicting evidence on whether lumbar corsets and support belts are effective for preventing or

reducing the impact of low back problems in subjects who do frequent lifting at work.

Traction

Panel findings and recommendations:

Spinal traction is not recommended in the treatment of patients with acute low back problems. (Strength of Evidence = B.)

Traction, when used for low back problems, involves the application of intermittent or continuous force along the axis of the spine in an attempt to elongate the spine by either mechanical or manual means. The most common type used for low back pain is pelvic traction, in which a snug girdle around the pelvis is attached to weights hung at the foot of the bed. The therapeutic objective of traction for patients with low back problems is to reduce pain.

Literature Reviewed. Of 31 articles screened for this topic, 7 articles reporting on 6 RCTs met criteria for review.[131,138,139,172-175] Another article contained information used by the panel, but did not meet selection criteria.[176]

Evidence on Efficacy. A meta-analysis of the studies on traction was done by the panel methodologists. Quality rating was done for the six RCTs reviewed without knowledge of study results. There were no excellent studies, one good study,[173] three fair studies,[131,139,172] a fair study reported on by Mathews, Mills, Jenkins, et al.,[138] and one poor study.[175]

All the studies involved patients with acute low back pain of less than 3 months' duration, but studies varied on whether patients with a history of previous low back problems were excluded. Groups receiving traction were

compared with groups receiving sham traction.[173,174] Traction combined with bed rest and corset use was compared with bed rest and corset use alone.[172] Traction was compared with heat[138] and with isometric exercise.[175] In addition, Coxhead, Meade, Inskip, et al.[131] studied groups receiving various combinations of traction, manipulation, exercise, and corset use in a multifactorial design with 16 cells. The six studies varied with respect to types of traction, control groups, outcome measures, and assessment periods. For this reason, no attempt was made to quantitatively combine these data.

Five of the six studies showed no difference between traction and the comparison group. In one study, the group treated with bed rest and corset use combined with traction had less pain at 1 week than those receiving bed rest and corset use without traction, but this difference was gone by 3 weeks.[172] Moreover, some criticize this study because of attention bias against those in the control group. In general, the studies did not indicate that traction in any form is beneficial in terms of pain relief, physiological status, length of hospital stay, functional outcome, or perception of overall improvement for patients with acute low back problems. The studies were too small to determine if traction actually harms patients with acute low back problems.

Potential Harms and Costs. The potential harms from traction relate to debilitation due to prolonged bed rest, including loss of muscle tone, bone demineralization, and the risk of thrombophlebitis. There is added risk of increased intraocular pressure and blood pressure with inverted hanging traction.[176] The cost of traction is considered low to moderate if it is done on an outpatient basis, or high if the patient is hospitalized for traction.

Summary of Findings. Evidence does not demonstrate traction to be effective in the treatment of patients with acute low back problems.

Biofeedback

Panel findings and recommendations:

Biofeedback is not recommended for treatment of patients with acute low back problems. (Strength of Evidence = C.)

Biofeedback involves translating the physiologic activity of a patient's muscular response into a visual or auditory signal that allows the patient to try to facilitate or inhibit the muscular activity. The therapeutic objective is to reduce muscle tension and thereby reduce pain. Biofeedback has been advocated primarily for patients with chronic low back problems.

Literature Reviewed. Of 13 articles screened for this topic, 4 reporting on 5 RCTs met criteria for review.[177-180] Other studies did not meet panel review criteria because they had fewer than 10 subjects per treatment group, but were used in a meta-analysis.[181,182] All of the studies involved patients with chronic low back pain. In most subjects, pain had persisted for several years.

Evidence on Efficacy. Because these trials presented conflicting results, a meta-analysis was begun by the panel methodologists. Studies were assessed for quality without knowledge of the results. There were no excellent studies, one good study,[178] three fair studies,[177,180,182] and a fair study reported by Flor, Haag, Turk, et al.[179] and by Flor, Haag, and Turk.[181] There were no poor studies.

The studies involved comparisons of biofeedback with sham biofeedback;[178,179,181] biofeedback combined with

another treatment in comparison with the other treatment alone;[177] and biofeedback alone compared with some other treatment. [179,181,182]

The study with a good quality rating showed no benefit for biofeedback over sham biofeedback.[178] Two studies reported patients in the biofeedback groups developed significantly better control of paraspinous muscle electromyographic activity.[178,180] In neither study did this reduce pain. Thus, of the five studies, two showed no benefit for biofeedback.[178,180] Two showed a benefit for biofeedback: Asfour, Khalil, Waly, et al.[177] and the study reported by Flor, Haag, Turk, et al.,[179] and by Flor, Haag, and Turk.[181] One study showed a slight benefit for biofeedback compared with a placebo condition, but reported an even better benefit for relaxation training.[182] Statistical combination of results from these studies was not done because it would require requesting the original data from the authors.

Conclusions from the attempted meta-analysis were that biofeedback as a treatment for low back problems has been studied only for chronic problems, and that most of the studies are of mediocre quality and arrive at conflicting results.

Potential Harms and Costs. The risks for biofeedback are considered low. The costs of biofeedback treatment are determined by the number of treatment visits.

Summary of Findings. There is conflicting evidence on the effectiveness of biofeedback for treating patients with chronic low back problems. However, this technique has not been studied in patients with acute low back problems.

Symptom Control: Injection Therapy

Trigger Point and Ligamentous Injections

Panel findings and recommendations:

- Trigger point injections are invasive and not recommended in the treatment of patients with acute low back problems. (Strength of Evidence = C.)

- Ligamentous and sclerosant injections are invasive and not recommended in the treatment of patients with acute low back problems. (Strength of Evidence = C.)

Trigger point injections involve the injection of local anesthetic into soft tissues (muscles) near localized tender points in the paravertebral area.[189] The theory that such trigger points are responsible for causing or perpetuating low back pain is controversial and disputed by many experts. Other articles reviewed for this topic involve the injection of various substances (especially sclerosing agents) into interspinal ligaments and ligamentous muscle attachments in the low back. The theory behind such treatment is that this stimulates formation of scar tissue in ligaments. The therapeutic objective of both trigger point injections and ligamentous injections is to reduce low back pain.

Literature Reviewed. Of 14 articles screened for the topics of trigger point and ligamentous injections, 6 RCTs met criteria for review. Three of these evaluated trigger point injections into muscle.[183-185] Three evaluated injections into ligamentous structures in the back.[186-188] Other articles contained information used by the panel, but did not meet article selection criteria.[189-190]

Evidence on Efficacy. Of the articles evaluating trigger point injections, only Frost, Jessen, and Siggaard-

Andersen[184] evaluated patients with acute low back problems. The study population, however, included patients with acute neck or shoulder pain, and data were not given separately for the patients with low back problems. For the other two RCTs on trigger point injections, either the patients evaluated had chronic low back problems[183] or the duration of symptoms was not reported.[185]

Various medications were used for trigger point injections. Frost, Jessen, and Siggaard-Andersen[184] had two groups receiving either local anesthetic or saline. Bourne[183] had three groups receiving methylprednisolone and lignocaine, or triamcinolone and lignocaine, or lignocaine alone. Garvey, Marks, and Wiesel[185] had four groups receiving lidocaine alone, or lidocaine combined with a steroid, or needle acupuncture (with no injection of material), or vapocoolant spray to the skin followed by acupressure (using a plastic needle guard). Two studies included control groups who had no medication injected into muscles,[184,185] but none of the three studies included a group with no intervention.

Frost, Jessen, and Siggaard-Andersen[184] and Garvey, Marks, and Wiesel[185] found no differences between groups in pain relief or other outcome measures on followup at 1 and 2 weeks posttreatment, respectively. Bourne[183] found significantly greater pain relief at 3 months followup for the two groups receiving steroid injections than for the group receiving injections of local anesthetic alone.

Of the three articles evaluating injections into ligamentous structures, two studies evaluated patient groups including some patients with acute low back problems.[186,188] One study evaluated a subgroup of patients with acute low back problems, all with pain over the medial iliac crest.[186] In the other study, patients were only described as having low back problems for greater than 1

month's duration without specifying how many patients had either acute or chronic symptoms.[188] The third article evaluating ligamentous injections evaluated only patients with chronic low back problems.[187]

Various substances were injected into different ligamentous structures of the low back. Collée, Dijkmans, Vandenbroucke, et al.[186] studied groups receiving injections of either local anesthetic or saline into an area of tenderness over the medial iliac crest (not specified if into muscle or ligamentous attachments). Ongley, Klein, Dorman, et al.[187] evaluated groups receiving injections of either a dilute phenol solution (sclerosing agent) or saline into the lumbar interspinal ligament. Sonne, Christensen, Hansen, et al.[188] evaluated groups receiving injections of either a combination of local anesthetic and steroid or saline alone into the iliolumbar ligament.

Collée, Dijkmans, Vandenbroucke, et al.[186] found that for patients with acute low back pain, there was no significant difference in pain relief between the saline or anesthetic groups, either immediately postinjection or at 1 or 2 weeks followup. Ongley, Klein, Dorman, et al.[187] found greater improvement in pain and disability scores for the patients receiving phenol injections (intended to induce scar) as compared with saline. Sonne, Christensen, Hansen, et al.[188] found that the group receiving injections with a combination of steroid and local anesthetic had significantly greater improvement in symptoms at 2 weeks followup than did the group receiving injections with saline.

Potential Harms and Costs. The potential risks of trigger point injections include damage to nerves or other tissues, infection, and hemorrhage.[190] The cost for this treatment is considered low to moderate.

Summary of Findings. Based on limited research evidence in studies that included patients with chronic problems, the efficacy of trigger point or ligamentous injections for treating acute low back problems appears equivocal. The injections can expose patients to serious potential complications.

Facet Joint Injections

Panel findings and recommendations:

Facet joint injections are invasive and not recommended for use in the treatment of patients with acute low back problems. (Strength of Evidence = C.)

In treatment of low back problems, facet joint injections involve the injection of local anesthetics and/or corticosteroids into or around facet joints of the lumbar spine, with needle placement aided by fluoroscopy. The theoretical basis is that some patients with low back problems have a "facet syndrome" with pain arising from facet joints. The facet syndrome reportedly involves patients with primarily low back pain (unilateral or bilateral) and no root tension signs or neurologic deficits, the pain usually being aggravated by extension of the spine.[191] The therapeutic objective of facet joint injections is temporary relief from motion-limiting pain so the patient may proceed into an appropriate exercise program.[198]

Literature Reviewed. Of 17 articles screened for this topic, 5 RCTs met review criteria.[191-195] Other articles contained information used by the panel, but did not meet criteria.[196,197]

Evidence on Efficacy. No articles were found evaluating patient groups who had only acute low back problems of less than 3 months' duration. One study evaluated a mixed

group of acute and chronic patients with pretreatment symptom durations ranging from 1 to 12 months.[191] Three articles evaluated patients with low back pain of over 3 months' duration.[192-194] One study did not specify symptom duration before treatment.[195]

Injections were made either into facet joints or into pericapsular areas around facet joints. The latter type of injection was also referred to as a "facet nerve block" when a local anesthetic was used. Medications injected included steroids, local anesthetics, and saline (either alone or in combination).

Three studies evaluated a combination of steroid and local anesthetic injected into either facet joints or pericapsular areas.[193-195] Three studies evaluated groups receiving facet joint injections in which steroid was compared with saline,[192] or local anesthetic was compared with saline,[191] or a combination of steroid and local anesthetic was compared with saline.[193]

None of the five studies that met review criteria found any significant differences between groups for patient-rated pain relief or global improvement scores during followup periods of up to 3 months after treatment. The only study with followup beyond 3 months found significantly greater improvement in pain and functional disability ratings at 6 months followup for the group receiving steroid facet injections compared with saline facet injections, but no significant differences between groups in number of patients who had sustained improvement over the entire 6-month followup period.[192]

Potential Harms and Costs. Some of the articles reviewed noted transient local pain at the injection sites. The risks of facet joint injections include potential infection, hemorrhage, neurologic damage, and chemical meningitis,[196,197] as well as

x-ray exposure from fluoroscopy. Facet injections are considered a moderate- to high-cost treatment.

Summary of Findings. No studies have adequately investigated the efficacy of facet injections for patients with acute low back problems. However, there were an adequate number of studies evaluating facet injections for chronic low back problems.[192-195] One study evaluated a mix of acute and chronic problems.[191] Neither the type of agent injected (steroid, local anesthetic, saline, or a combination of these) nor the location of the injection (intrafacet or pericapsular) made a significant difference in patient outcomes during the first 3 months after treatment or in the percentage of patients with sustained improvement over 6 months.

Based on limited research evidence, facet joint injections appear to be associated with rare potential serious complications and do not appear to be effective for treating acute low back problems.

Epidural Injections (Steroids, Lidocaine, Opioids)

Panel findings and recommendations:

- There is no evidence to support the use of invasive epidural injections of steroids, local anesthetics, and/or opioids as a treatment for acute low back pain without radiculopathy. (Strength of Evidence = D.)

- Epidural steroid injections are an option for short-term relief of radicular pain after failure of conservative treatment and as a means of avoiding surgery. (Strength of Evidence = C.)

Epidural injections for treating low back problems, done primarily in patients with suspected radiculopathy, involve the injection of medication (corticosteroids, local anesthetics,

or narcotics) into the epidural space, near the site where the nerve roots pass before entering the intervertebral foramen. In theory, injecting medication into the epidural space allows a concentrated amount of medication to be deposited and retained in a specific area, exposing the nerves to the medication for a prolonged period of time. The therapeutic objective of epidural injections is to reduce swelling, inflammation, and pain.

There are various techniques for performing the epidural injection, some of which are more precise than others.[198] According to White,[199] placement of epidural needles is incorrect in 25 percent of the cases.

Literature Reviewed. Of 74 articles screened for this topic, 9 RCTs met criteria for review.[138,200-207] Other articles contained information used by the panel, but did not meet article selection criteria.[147,198,199,208,209]

Evidence on Efficacy. Two studies evaluated patients with acute low back pain of less than 3 months' duration and also with radicular symptoms and findings suggesting nerve root dysfunction.[138,202] Both studies compared groups receiving epidural injections of steroids combined with local anesthetic to groups receiving injections of local anesthetic alone, either into the epidural space[202] or into a tender spot over the sacrum.[138]

Cuckler, Bernini, Wiesel, et al.[202] found no significant differences in pain relief between groups immediately posttreatment or at long-term followup (mean of 20 months). Mathews, Mills, Jenkins, et al.[138] found no significant differences in pain relief between groups at 1, 6, or 12 months followup, but the epidural steroid group did have significantly better results at 3 months followup.

The remaining seven studies evaluated groups with either chronic low back problems or a mix of acute and chronic problems.[200,201,203-207] Medications used and locations injected varied. Four studies evaluated groups receiving epidural injections with various combinations of steroids, local anesthetics, and/or saline.[200,201,205,207] Two studies evaluated groups receiving either epidural steroid injections or injections of saline into the interspinous ligament.[204,206] One study evaluated groups receiving epidural injections with various combinations of steroids and morphine.[203]

The five studies that reported on short-term pain relief at 2 to 4 weeks followup showed conflicting results. For this time period, three studies reported significantly greater pain relief for the epidural steroid groups.[201,204,206] The other two studies found no differences in pain relief between groups.[205,207]

Five studies reported on followup beyond 1 month.[200,201,204,205,207] Only one found significantly greater pain relief for the epidural steroid group.[200] The other studies found no significant differences in pain relief between groups. One study did find that a significantly higher percentage of the group receiving epidural steroid injections had returned to work at 3 months.[204] Three studies showed significantly better results within the first month for epidural steroids versus local anesthetic or saline injections, but not on longer followup.[201,204,206] No significant differences were reported between groups at 3 months[204] or at 1 year.[201] Ridley, Kingsley, Gibson, et al.[206] did not report followup beyond 2 weeks. Two other studies found no significant differences in pain relief between groups for any followup period.[205,207] One study that evaluated epidural injections of morphine compared with (and/or in combination with) steroids found no significant differences in pain relief between groups on either short-term (within 1 month) or longer term followup.[203]

Potential Harms and Costs. Reported complications of epidural injections are described by Kepes and Duncalf.[208] The primary major complication reported was rare epidural abscess. Minor transient complications included headache, fever, and inadvertent spinal tap. Rocco, Frank, Kaul, et al.[209] reported several cases of life-threatening ventilatory depression in patients who received epidural injections of morphine and steroids combined. In 5 of the 19 times such injections were given, the patients experienced respiratory depression to the point of somnolence and had to receive naloxone for reversal of narcosis. Also posttreatment, the respiratory rates of patients receiving epidural morphine were lower than for patients receiving epidural steroids alone. The lowest respiratory rates were seen in those receiving injections of morphine combined with steroids. Mandell, Lipton, Bernstein, et al.[147] described headache as the most common side effect of epidural steroid injections (presumably resulting from pressure changes in the epidural space or accidental puncture of the dura) and listed aseptic meningitis, infection, and neurologic problems as other possible complications. Epidural injections are considered an expensive treatment.

Summary of Findings. Limited research evidence indicates that epidural injections using any type of medication lack proven efficacy for treating patients with acute low back pain without radiculopathy. Epidural injections are invasive and pose rare but serious potential risks. There was no evidence that epidural steroids are effective in treating acute radiculopathy, but the panel's opinion was that epidural steroid injections may be useful as an attempt to avoid surgery.

Acupuncture

Panel findings and recommendations:

Invasive needle acupuncture and other dry needling techniques are not recommended for treating patients with acute low back problems. (Strength of Evidence = D.)

Acupuncture is defined here to include all types of "dry needling" procedures (where no medication is injected) into cutaneous and subcutaneous tissues, muscles, or ligaments. Traditional acupuncture, based on Chinese philosophy, requires that needles be inserted into specific areas of the body (the prescribed Chinese meridians) and that these needles be rotated to produce a noxious stimulus. Other types of dry needling involve needle insertion without regard for the Chinese meridians into tender spots or other areas and may or may not involve the rotation of the needles. Some dry needling techniques also add electrical stimulation to the needles. The therapeutic objective of acupuncture and other dry needling techniques is to reduce pain.

Literature Reviewed. Of 24 articles screened for this topic, 8 reporting on 6 RCTs met criteria for review.[161,162,210-215] The panel also examined a meta-analysis.[216] Other articles contained information used by the panel, but did not meet article selection criteria.[217-220]

Evidence on Efficacy. All six RCTs evaluated patients with chronic back problems (with or without leg symptoms) of greater than 6 months' duration. Four of the articles reporting on three RCTs compared groups that received needling with groups that received no needling.[161,162,210,213] Needling received was either acupuncture in traditional Chinese meridians[161,162,210] or needle insertion into tender muscle points.[213] In these studies, the groups that received

some type of needling intervention had significantly better outcomes (in pain reduction and increased activity levels) than did the groups receiving no needling.

The remaining four articles reporting on three RCTs compared groups receiving acupuncture in the traditional Chinese meridians to groups receiving various types of needle insertion in other parts of the back.[211-215] None of these studies found any significant differences between groups in any outcomes measured.

A meta-analysis, based on 51 clinical studies on acupuncture used for various types of chronic pain (including back pain), found that the quality of even the better studies was mediocre and their results highly contradictory.[216] Specifically noted was that most of these studies did not provide an appropriate control group or were not adequately blinded. None of the studies demonstrated an advantage of needling in the appropriate Chinese meridians over misplaced needling. In this meta-analysis, the authors concluded that the efficacy of acupuncture for treatment of chronic pain remains doubtful.

Potential Harms and Costs. Reported complications of acupuncture include hematomas, infections (hepatitis B and Staphylococcus aureus), pneumothorax, and spinal nerve and spinal cord injuries due to buried needles migrating to the spinal cord.[217-220] In addition, the panel offered the opinion that needle insertion treatments involve some discomfort. Costs of acupuncture and other dry needling treatments vary depending on the number of treatment visits.

Summary of Findings. No studies were found evaluating efficacy of acupuncture in patients with acute low back problems. In three of the six RCTs evaluating efficacy for chronic low back problems, outcomes were better for the

acupuncture group than for nontreatment control groups. All studies had methodologic flaws. Acupuncture was also found to have risks of significant complications.

Activity Modification

Activity Recommendations

Panel findings and recommendations:

- Patients with acute low back problems may be more comfortable if they temporarily limit or avoid specific activities known to increase mechanical stress on the spine, especially prolonged unsupported sitting, heavy lifting, and bending or twisting the back while lifting. (Strength of Evidence = D.)

- Activity recommendations for the employed patient with acute low back symptoms need to consider the patient's age and general health, and the physical demands of required job tasks. (Strength of Evidence = D.)

Patients with acute low back problems frequently seek advice from clinicians about the physical activities they can "safely" perform. Employed patients, or their employers, also often ask health care providers to recommend work restrictions that will allow the patient to remain on the job during an episode of acute low back symptoms. Activity modifications are aimed at allowing the patient with an acute low back problem to achieve a tolerable comfort level while continuing adequate physical activity to avoid debilitation. The overall goal is to aid recovery while disrupting daily activities as little as possible.

Literature Reviewed. Of the articles screened dealing with work and other activity modifications for patients with acute low back problems, none met established panel review

criteria for adequate evidence about efficacy. However, eight articles were considered by the panel to contain useful information on these issues.[221-228]

Evidence on Efficacy. A number of epidemiological studies have looked at risk factors associated with developing acute low back problems. Although there is no clear consensus on the role of these factors, several studies have identified an increased incidence of low back problems among individuals whose work involves heavy or repetitive lifting, exposure to total body vibration (from vehicles or industrial machinery), asymmetric postures, and postures sustained for long periods of time.[222,225]

Other biomechanical research suggests that certain postures and activities increase the mechanical stress on the spine.[221,223,225] It is not clear whether these mechanical stresses are the cause of low back problems. However, once symptoms are present, mechanical stresses correlate with worsening of symptoms. Prolonged sitting and postures that involve bending and twisting have been shown to increase the mechanical stress on the spine according to pressure measurements in lumbar intervertebral discs. Heavy lifting also appears to increase mechanical stress on the spine, but this stress can be reduced if the lifted object is held close to the body rather than at arm's length.

A lifting equation to calculate appropriate lifting limits for various tasks was part of a guideline developed in 1981 by the National Institute of Occupational Safety and Health[227] and revised more recently.[228] Unfortunately, the ability of the guideline to reduce the incidence of low back problems has yet to be directly validated. Other ergonomic guidelines for safe lifting have been reviewed by Dul and Hildebrandt.[224]

Summary of Findings. While scientific information is limited, the panel felt that activity modifications represented an important practical issue for the clinician. The panel's recommendations are based on their interpretation of the available scientific data. Patients with acute low back problems can be advised to limit temporarily any heavy lifting, prolonged sitting, and bending or twisting the back since these activities have been shown to increase mechanical stress on the spine.

In recommending activity modifications for patients who work, the clinician may find it helpful to obtain from the employer a description of the physical demands of required job tasks. The nature and duration of limitations will depend on the clinical status of the patient and the physical requirements of the job. Activity modifications must be time-limited, clear to both patient and employer, and reviewed by the clinician on a regular basis.

Several ergonomic guidelines on lifting and materials-handling tasks are available to help the clinician provide ranges of activity alterations at work. These guidelines are based on various biomechanical assumptions and theoretical equations to build a margin of safety for individuals who have to lift at work. It should be remembered that such guidelines were developed or otherwise healthy workers and are therefore of limited use in making strict recommendations. None of these guidelines has been adequately tested to see if adherence will reduce the occurrence of low back problems.

The panel recommends that clinicians help patients establish activity goals, in consultation with their employer when applicable. Such goals are particularly important for the small percentage of patients who are still not able to overcome activity intolerance after 1 to 2 months of symptoms. Since nonphysical factors, such as emotional

distress or low work satisfaction, may also affect an individual's symptoms and response to treatment, activity goals can help keep attention focused on the expected return to full functional status and emphasize physical conditioning to improve activity tolerance.

Bed Rest

Panel findings and recommendations:

- A gradual return to normal activities is more effective than prolonged bed rest for treating acute low back problems. (Strength of Evidence = B.)

- Prolonged bed rest for more than 4 days may lead to debilitation and is not recommended for treating acute low back problems. (Strength of Evidence = B.)

- The majority of low back patients will not require bed rest. Bed rest for 2 to 4 days may be an option for patients with severe initial symptoms of primarily leg pain. (Strength of Evidence = D.)

Bed rest is a frequently used treatment for acute low back pain. The therapeutic objective is to relieve symptoms by reducing intradiscal pressure and/or pressure on nerve roots. Studies have shown that intradiscal pressures are lowest when subjects are lying supine in the semi-Fowler position, on the back with hips and knees moderately flexed.[8]

Literature Reviewed. Of 12 articles screened for this topic, 5 reporting on 4 RCTs met criteria for review.[75,85,117,229,230] All these studies evaluated patients with acute low back problems. Other articles contained information used by the panel, but did not meet selection criteria.[8,231,232]

Evidence on Efficacy. Evidence is limited regarding efficacy of bed rest versus no treatment for patients with acute low back problems. One study involving military recruits compared forced bed rest to an alternative treatment of forced ambulation.[117] Although the bed rest group returned to full activity sooner, methodological problems with this study made interpretation difficult. Outcome assessments were not blinded, and patients in the hospitalized group were deprived of their peer-group activities, possibly confounding results. Two articles compared groups receiving either a recommendation for bed rest (of at least 4 days duration) or some other treatment (such as exercise, education, or manipulation) but no bed rest recommendation.[75,85,230] These two articles found no statistically significant differences between bed rest and other treatment modalities. Bed rest of more than 4 days and the resulting deactivation were worse for patients than a gradual return to normal levels of activity. Deyo, Diehl, and Rosenthal[229] compared two groups receiving recommendations for either 2 days or 7 days of bed rest. No differences were found between the groups in pain relief or in time to resumption of normal activities, except for earlier return to work in the 2-day group for those employed at baseline.

One problem with these studies is that the actual amount of bed rest reported by the subjects often differed greatly from the amount recommended. Deyo, Diehl, and Rosenthal[229] found that 74 percent of the 99 subjects assigned to the 7-day bed rest group reported fewer than 7 days of actual bed rest. The study reported by Evans, Gilbert, Taylor, et al.[75] and Gilbert, Taylor, Hildebrand, et al.[230] found that subjects who did not receive a bed rest recommendation also reported trying bed rest, but the duration was less than for the group receiving the recommendation.

Potential Harms and Costs. Potential physical side effects from prolonged bed rest are many, including muscle atrophy (1.0 to 1.5 percent of muscle mass lost per day), cardiopulmonary deconditioning (15-percent loss in aerobic capacity in 10 days), bone mineral loss with hypercalcemia and hypercalciuria, and the risk of thromboembolism.[232] There are also social side effects, such as perception of severe illness and economic loss due to increased time lost from work.[231]

Summary of Findings. There is no evidence to support the efficacy of bed rest compared with no treatment in patients with acute low back problems. Deactivation resulting from prolonged bed rest (more than 2 to 4 days) appears to be worse for patients than a gradual return to normal levels of activity.

Exercise

Panel recommendations and findings:

- Low-stress aerobic exercise can prevent debilitation due to inactivity during the first month of symptoms and thereafter may help to return patients to the highest level of functioning appropriate to their circumstances. (Strength of Evidence = C.)

- Aerobic (endurance) exercise programs, which minimally stress the back (walking, biking, or swimming), can be started during the first 2 weeks for most patients with acute low back problems. (Strength of Evidence = D.) Conditioning exercises for trunk muscles (especially back extensors), gradually increased, are helpful for patients with acute low back problems, especially if symptoms persist. During the first 2 weeks, these exercises may aggravate symptoms since they

mechanically stress the back more than endurance exercises. (Strength of Evidence = C.)

- Back-specific exercise machines provide no apparent benefit over traditional exercise in the treatment of patients with acute low back problems. (Strength of Evidence = D.)

- Evidence does not support stretching of the back muscles in the treatment of patients with acute low back problems. (Strength of Evidence = D.)

- Recommended exercise quotas that are gradually increased result in better outcomes than telling patients to stop exercising if pain occurs. (Strength of Evidence = C.)

Various types of exercise programs have been advocated for patients with low back problems. The most commonly studied types focus on back flexion, back extension, generalized strengthening, endurance (aerobic conditioning), stretching, or some combination of these. Authors also reported exercises for low back problems as dynamic (isotonic) and static (isometric). Most of these exercises can be either taught to the patient for home use or performed under supervision in a clinical setting. Commonly reported therapeutic objectives of exercise programs for low back problems are improvements in endurance, muscle strength, and flexibility presumably leading to reduced symptoms, improved level of functioning, and fewer or less severe future back problems.

Literature Reviewed. Of 92 articles screened, 20 RCTs met criteria for review.[74,75,81,83,84,86,131,155,157,233-243]

Other articles contained information used by the panel, but did not meet article selection criteria.[221,226,232,244-253]

Only six of the articles reviewed involved studies of exercise as a treatment for patients with acute low back problems.[75,83,86,131,234,243]

Two other studies evaluated the efficacy of exercises for preventing or reducing the impact of low back problems in workers whose jobs involved frequent lifting.[236,237] The remaining articles all evaluated exercise as a treatment for groups that contained only patients with chronic pain or a mix of patients with acute and chronic problems. These were given less weight by the panel as there were enough studies using patients with acute low back problems.

Evidence on Efficacy. Of the six articles evaluating patients with acute low back problems, only one was considered well designed.[83] Swedish auto workers who had been off work for 6 weeks due to low back problems were randomized to either a control group with no recommendations for exercise or an exercise group with a program of gradually increased aerobic and back-strengthening exercises. At 1-year followup, patients in the exercise group had lost significantly less time from work due to back pain and had achieved a significantly higher level of fitness compared with the control group.

The other five articles dealing with acute low back problems included interventions that made the effect of exercise difficult to determine.[75,86,131,234,243]

Stankovic and Johnell[86] compared McKenzie extension exercises to a 45-minute educational session and found that the exercise group stopped medication use earlier and reported more pain relief and fewer days off work. Evans, Gilbert, Taylor, et al.[75] found that patients who received a flexion exercise program plus a 30-minute educational program stopped using medication sooner than did patients in bed rest and control groups. However, no differences

were found between groups in reported degree of pain relief or activities of daily living.

The other three of these five studies showed no significant differences in outcomes between the treatment groups.[131,234,243]

Davies, Gibson, and Tester[234] compared groups receiving short-term diathermy and either extension or flexion exercises. Zylbergold and Piper[243] compared flexion exercises to manual therapy in combination with home back care instructions. Coxhead, Meade, Inskip, et al.[131] compared groups receiving various combinations of exercise (not otherwise specified), traction, manipulation, and lumbar corset use in a multifactorial study with 16 cells.

In summary, the six studies, which evaluated exercise for treating acute low back problems, used different forms of flexion or extension exercises, different treatment or control groups, different outcome measures, and different assessment periods. For this reason, no attempt was made to quantitatively combine these data.

As noted previously, two studies evaluated exercise for preventing acute or recurrent episodes of low back problems. Gundewall, Liljeqvist, and Hansson,[236] in a RCT, evaluated 60 nursing personnel working at a geriatric hospital. Subjects were randomized to receive either no intervention or a supervised exercise program during work six times per month for 13 months (emphasizing isometric and dynamic exercises strengthening the back extensor muscles).

At the end of the study, the exercise group had a significantly lower incidence of new low back problem episodes when compared with the control group (4 percent compared with 38 percent), fewer days lost from work,

fewer days with back pain complaints, and a lower average duration of low back pain complaints. Trunk extensor strength measured with a spring gauge was not different between groups at the start of the study, but at the end of the study average trunk strength was significantly greater in the exercise group compared with the control group. The authors noted that the exercise group did receive more attention than the control group, which could account for some of the positive effect. Results were not reported separately for those with and without prior low back problems.

In the second study, Kellett, Kellett, and Nordholm,[237] in a RCT, evaluated 60 workers at a kitchen cabinet manufacturing company in Sweden. All were working at the start of the study and reported having either current or prior back pain. Subjects were randomly assigned to a control group or an exercise group. The exercise group was offered an exercise program at work once per week (30 minutes of aerobic movements of the arms, legs, and trunk followed by 10 minutes of relaxation) and were asked to do 30 minutes of aerobic exercise (such as walking, jogging, or cycling) on their own at least once per week.

Although subjects in the exercise group were encouraged to progressively increase their effort level during exercise, no direct measures of exertion (such as heart rate) were recorded. The exercise group was also given lectures about back problems and proper lifting techniques. There were no significant differences between exercise and control groups in incidence rates or days lost from work for episodes of back pain in the 1.5 years before the intervention. The incidence rate and days lost from work for episodes of back pain decreased in the exercise group during the subsequent 1.5-year intervention period. In the control group, absenteeism attributable to back pain increased during the intervention period. There were no

significant differences, either before or after the study, between groups in cardiovascular fitness as measured by a suboptimal bicycle ergometer.

Deyo[232] remarked that, although there seems to be a consensus among experts that exercise plays a major role in the treatment of low back symptoms, most treatment programs prescribe a combination of exercises and there is little agreement on specific regimens. He also offered an opinion that additional benefits of aerobic exercise may include weight loss and favorable psychological effects, such as reduction of anxiety and depression. Other studies have shown that patients improve faster when given specific quotas of exercises to do rather than being told to stop exercise when it produces pain.[83,246]

One study[251] found a back-specific exercise machine (the B-200) does not provide added benefit over traditional exercise in improving the objective back strength and flexibility (as measured by functional lifting capacity) of low back patients.

Potential Harms and Costs. Potential harms of exercise are usually not discussed. However, one RCT found that extension exercises caused increased symptoms in chronic low back pain patients.[238] Another study suggests that abdominal flexion (Williams flexion) exercises and stretching can increase mechanical stress on the spine as observed by intradiscal pressure measurements.[248]

Many methods have been proposed to evaluate mechanical stress on the back in different postures and activities.[221,226,244,245,247-250,252] A biomechanical model by Schultz directly correlates with in vivo measurements of intradiscal pressure and myoelectric signals.[253] The measurements of relative stress on the spine during postures and activities generally relate to increased and

decreased symptoms experienced by patients with back problems. Thus, this information can be used for recommendations about safety and altering activity. The costs of exercise programs can vary depending upon the setting. Those performed at home are inexpensive, whereas those done in supervised clinical settings are more costly. Exercise programs using back-specific computerized exercise machines can be very expensive. No studies meeting review criteria were found that provided evidence of any of these exercise settings being more effective than the others.

Summary of Findings. There are only a few RCTs that have evaluated exercise as a treatment for acute low back problems, and these are limited by small numbers of patients and inadequate descriptions of specific exercise regimens. The one well-designed RCT of patients limited for less than 3 months by low back symptoms found that a program of gradually increased aerobic and back-strengthening exercises was superior to doing no exercise at all.[83]

Exercise programs aimed at improving general endurance (aerobic fitness) and muscular strength (especially of the back and abdomen) have been shown in some published studies to benefit patients with acute low back problems. No evidence supports stretching as effective treatment for acute low back problems. The panel offered the opinion that patients with acute low back problems would benefit from exercise programs if endurance programs are started early, using exercises that cause minimal mechanical stress on the back; if patients are given set exercise quotas gradually increased with time; and if later strengthening programs are individualized based on the level of activity to which patients wish to return. The panel suggested that the early goal of exercise programs is to prevent debilitation due to inactivity and then to improve

activity tolerance to return patients to their highest level of functioning as soon as possible.

4. Special Studies and Diagnostic Considerations

After the first month of symptoms, the vast majority of patients have recovered from activity limitations due to low back problems. However, if the patient is limited by back symptoms for more than 1 month, special diagnostic and treatment procedures are often considered to find a reason for the slow recovery (Attachment A3).

The special studies are of two kinds. First are tests to provide evidence of physiologic dysfunction such as neurologic dysfunction, infection, inflammation, malignancy, or other systemic illness. Second are tests to define a potential anatomic reason for the dysfunction such as a herniated lumbar disc, spinal stenosis, infection, tumor, or abdominal mass. As a result of diagnostic considerations, therapeutic interventions including surgery may be recommended.

Except when serious underlying pathology is suspected, special diagnostic tests are usually not needed during the first month because it is not possible to predict early on which patients will and will not improve during this period. But those who are not improving at 1 month may include some who could benefit from specific therapeutic interventions. Waiting longer to start the diagnostic workup may delay recovery for these individuals.

Special Studies: Tests for Evidence of Physiologic Dysfunction

Tests commonly used to identify focal neurologic physiologic dysfunction include electromyography (EMG), sensory evoked potentials (SEPs), and thermography. To detect physiologic dysfunction of nonneurologic diseases,

general laboratory screening tests, such as erythrocyte sedimentation rate (ESR), complete blood count (CBC), and urinalysis (UA), and bone scan have been proposed.

Electrophysiologic Tests (EMG and SEP)

Panel findings and recommendations:

- Needle EMG and H-reflex tests of the lower limb may be useful in assessing questionable nerve root dysfunction in patients with leg symptoms lasting longer than 4 weeks (regardless of whether patients also have back pain). (Strength of Evidence = C.)

- If the diagnosis of radiculopathy is obvious and specific on clinical examination, electrophysiologic testing is not recommended. (Strength of Evidence = D.)

- Surface EMG and F-wave tests are not recommended for assessing patients with acute low back symptoms. (Strength of Evidence = C.)

- SEPs may be useful in assessing suspected spinal stenosis and spinal cord myelopathy. (Strength of Evidence = C.)

Electrophysiologic tests are sometimes used in patients with sciatica to evaluate physiologic functioning of the spinal cord, nerve roots, and peripheral nerves. Overall diagnostic objectives of these tests are to assess suspected myelopathy (dysfunction of the spinal cord), radiculopathy (dysfunction of a spinal nerve root), neuropathy (dysfunction of a peripheral nerve distal to the nerve root), and myopathy (muscle abnormalities). The tests and their specific diagnostic objectives for low back problems are as follows:

- Needle electromyography (EMG), used to assess acute and chronic nerve root dysfunction, myelopathy, and myopathy.

- H-reflex, a test measuring sensory conduction through nerve roots, used mostly to assess S- [1] radiculopathies.

- F-wave response, a test measuring motor conduction through nerve roots, used to assess proximal neuropathies.

- Surface EMG, used to assess acute and chronic recruitment patterns during static or dynamic tasks using surface electrodes instead of needle insertion.

- SEPs, used to assess sensory neurons in peripheral and spinal cord pathways.

- Nerve conduction studies, used to assess acute and chronic peripheral entrapment neuropathies that may mimic radiculopathies.

Literature Reviewed. Of 52 articles screened for this topic, 8 met review criteria for adequate evidence about efficacy.[21,254-260] Also reviewed was one study that evaluated findings in asymptomatic subjects who had no history of low back problems.[261] Other studies contained information used by the panel.[49,20,147]

Four studies evaluated needle EMG.[21,254,257,260] Three studies evaluated H-reflex or F-wave tests.[21,254,256] Two studies evaluated surface EMG.[258,261] One study evaluated SEPs.[259] No studies were found evaluating nerve conduction for assessing low back problems. All articles meeting review criteria involved groups of patients either with chronic problems or with unreported symptom duration.

Evidence on Efficacy. Reference tests used to determine diagnostic accuracy (true positive and true negative rates) of needle EMG included surgical findings.[21,254,260] They also included clinical followup (pain rating and work status), with posttest at 1 year.[257] The amount and quality of data that could be used to calculate diagnostic accuracy of these tests varied significantly between studies. Many studies had major methodological flaws such as biased test interpretations, faulty cohort assembly, and poor clinical descriptions. Determining the accuracy of EMG is difficult as well because anatomic defects seen at surgery, which are used in many of these studies as the reference standard for EMG, may or may not be the cause of symptoms. This makes true positive and true negative rate determinations of questionable value.

For *needle* EMG, four articles evaluated the test's accuracy in diagnosing nerve root problems. Aiello, Serra, Migliore, et al.[21] evaluated 25 patients who had clinical evidence of L3 and/or L4 nerve root impairment. Needle EMG was abnormal in all 24 patients who had positive findings at surgery, but predicted the exact levels of nerve root pathology in only 9 percent of these 24 patients. One patient had a false-positive EMG with no disc herniation found at surgery.

Aiello, Serra, Tugnoli, et al.[254] evaluated the accuracy of EMG for detecting and localizing nerve root compromise in patients who had surgical findings of a single lumbar disc prolapse at the L3-L4 level (100-percent true positive rate, 88-percent true negative rate), with disc herniation at L4-L5 (96-percent true positive rate, 38-percent true negative rate) and with disc herniation L5-S1 (71-percent true positive rate, 79-percent true negative rate).

Khatri, Baruah, and McQuillen[257] evaluated outcomes at 1 year in patients with radicular leg pain who had needle

EMGs and computerized tomography (CT) scans and then went on to have disc surgery or nonsurgical treatment (including conservative care and/or epidural steroids). There were 35 patients who had abnormal EMGs and CT scan findings of a herniated lumbar disc. Of the 16 patients treated with surgery, 81 percent were better at 1 year, while of the 19 who had nonsurgical treatments only 47 percent reported improvement at one year. There were 24 patients whose EMGs and CT scans were both normal; none of these patients had surgery, and at 1-year followup 67 percent were improved.

Young, Getty, Jackson, et al.[260] evaluated 100 patients with clinical evidence of L5 or S1 radiculopathy and found that needle EMG correctly predicted the level of nerve root pathology in 84 percent of the 95 patients with positive surgical findings. The wrong level was predicted in seven patients, and in nine patients only one abnormal root was detected when two were involved. EMGs were negative in all five patients who had no root pathology noted at surgery.

In cases of radiculopathy or neuropathy, EMG results may be unreliable in limb muscles until a patient has had significant leg symptoms for over 3 weeks. Also, abnormal EMGs tend to normalize over time. There is some evidence that greater accuracy can be obtained in diagnosing lumbar nerve root compromise when information from needle EMG is combined in a systematic fashion with information from imaging tests and clinical findings, rather than relying on the results of each test alone.[49,50]

For *H-reflex and F-wave tests,* three articles reported on accuracy in diagnosing nerve root problems. Aiello, Serra, Migliore, et al.[21] evaluated 25 patients with clinical evidence of L3 and/or L4 nerve root impairment. H-reflex tests were abnormal on the affected side in 96 percent of the 24 patients

with L3 and/or L4 nerve root compromise confirmed at surgery, but the test was also positive in the 1 patient with no nerve root pathology noted at surgery (96-percent true positive rate, 0-percent true negative rate).

Aiello, Serra, Tugnoli, et al.[254] evaluated H-reflex tests and EMGs for 50 patients in whom a single disc prolapse was found at surgery. H-reflex tests were positive in 71 percent of 7 patients with L3-L4 disc herniations, 58 percent of 26 patients with L4-L5 disc herniations, and 100 percent of 17 patients with L5-S1 disc herniations. In addition, by combining information from H-reflex tests and needle EMG, 30 percent of single disc prolapses could be determined accurately.

Braddom and Johnson[256] evaluated H-reflex tests in 25 patients with clinically suspected S1 radiculopathy. A normal range was established in 100 asymptomatic subjects. All 25 patients had H-reflex-test latencies greater than 2 standard deviations above the mean for the control group. Only three patients were reported as having surgery, and long-term followup results were not given.

For *surface* EMG, two articles evaluated efficacy in assessing patients with low back symptoms. Arena, Sherman, Bruno, et al.[255] evaluated surface EMG of lumbar paraspinal muscles as a function of pain state. Surface EMG results were not significantly able to differentiate back pain patients with high pain states from those in low pain states. Sihvonen, Partanen, Hanninen, et al.[258] evaluated both needle and surface EMG of lumbar paraspinal muscles in 87 patients with back pain (not radiculopathy) longer than 6 months, but who had not had surgery, and in 25 controls with no history of back problems. When compared to the asymptomatic controls, the patients with back pain had significantly increased surface EMG activity while standing and immediately after lumbar flexion.

For *SEPs,* the only article reviewed[259] evaluated accuracy in 18 patients with clinical findings of suspected spinal stenosis who went on to have surgery. At operation, all patients were found to have spinal stenosis. In all but 1 of the 18, SEPs had been positive (94-percent rate).

Potential Harms and Costs. Inserting small needle electrodes into muscle tissue is invasive, causes some patients discomfort, and may cause bruising. Patients who have severe pain, low pain thresholds, excessive anxiety, or conflicting emotional symptoms may not be able to participate fully in the examination.[147] EMG and other electrophysiologic tests are moderately expensive.

Summary of Findings. The evidence suggests that in patients with low back problems who have a confusing clinical picture of severe leg symptoms of more than 3 to 4 weeks' duration, EMG and H-reflex tests appear to be useful (1) to document presence or absence of radiculopathy or neuropathy as the cause of symptoms in the lower extremities, (2) to provide more information on specific nerve roots that may be compromised, and (3) to help differentiate between acute and chronic nerve root dysfunction. Optimal time for needle-EMG testing is after the patient has had lower limb symptoms at least 3 to 4 weeks. Test results are not reliable before this time.

SEPs appear to be useful in diagnosing spinal stenosis and spinal cord myelopathy. However, F-wave tests and surface EMGs are not considered effective methods of assessing acute low back problems.

Accuracy of electrophysiologic testing is highly dependent on the skill with which the examination is performed. Clinicians are urged to assess the qualifications of the diagnostician before referring a patient with suspected neurologic compromise.

Bone Scan

Panel findings and recommendations:

A bone scan is recommended to evaluate acute low back problems when spinal tumor, infection, or occult fracture is suspected from red flags on medical history, physical examination, or collaborative lab test or plain x-ray findings. Bone scans are contraindicated during pregnancy. (Strength of Evidence = C.)

Bone scanning, a type of radionuclide imaging, involves intravenous injection of radioactive compounds known to adhere to metabolically active bone. Gamma detectors localize regions of uptake. Most of the bone-seeking compounds used contain the radionuclide technetium- 99m. The diagnostic objective is to detect occult fractures, infections, and bony metastases of the spine and to differentiate them from common benign pathology such as degenerative changes.

Literature Reviewed. Of 26 articles screened for this topic, 5 met criteria for review.[262-266]

Evidence on Efficacy. In the studies reviewed, bone scan was used to detect several different clinical conditions: stress fracture injuries of the pars interarticularis;[263] inflammatory sacroiliitis;[262,264] spine infections;[266] metastatic cancer and other systemic disease;[265] and symptomatic spondylolysis.[263] All of these studies either evaluated mixed patient groups with both acute and chronic problems or did not report symptom duration.[264,265] There were no studies focusing specifically on patients with acute low back pain.

The reference standard used depended on the clinical condition to be assessed. Included were: clinical

diagnoses;[262-264] clinical followup or autopsy;[265] and biopsy with microbial cultures.[266]

Schütte and Park[265] evaluated bone scans for two groups. One group comprised 138 patients with a history of malignancy. In the other group, 38 patients with no previously recognized systemic disease had nonspecific low back pain and normal x-rays, but with strong clinical suspicion of an underlying serious condition causing the back pain. Of these 38 patients with "nonspecific" low back pain, 14 (37 percent) were later found to have a systemic disease. Of the 14 patients, 13 had elevated ESRs, but only 7 had positive bone scans (all 7 also with high ESRs). Of patients with a history of malignancy, 40 percent had positive bone scans determined on followup to be metastases and 14 percent had osteoporotic rib or vertebral fractures.

The authors concluded that bone scan has a high yield in patients with known malignancy. In patients where clinical suspicion of an underlying serious problem was high, but who had no known malignancy and normal x-rays, ESR detected 93 percent of those with systemic disease. Bone scan detected only 50 percent of these cases. The authors concluded that bone scan has a low yield in patients with longstanding low back problems and normal x-rays and lab tests.

Whalen, Brown, McLeod, et al.[266] evaluated patients with low back pain who had extensive diagnostic workups because of suspected spinal infections, and who then had open biopsy or percutaneous needle aspiration for culture and microbiologic diagnosis. Duration of symptoms before workup ranged from 2 weeks to 4 years (37 percent with symptoms for less than 3 months). One subgroup of 19 patients had all of these tests before spinal biopsy: technetium- 99m (Tc- 99m) bone scan, indium- 111 (In- 111)

white blood cell (WBC) bone scan, plain lumbar x-rays, and ESR. Of the 19 patients, 16 had spinal infections confirmed on culture of biopsy material.

For the 16 patients, true positive rates were: 81 percent for Tc-99m bone scan, 19 percent for In-111 WBC bone scan, 44 percent for plain x-rays, 82 percent for ESR > 20, and 56 percent for ESR > 50. False-negative rates for diagnosing spinal infection were: 3 of 3 (100 percent) for Tc-99m bone scan, 14 of 17 (82 percent) for In-111 WBC bone scan, 8 of 11 (73 percent) for plain x-rays, 2 of 2 (100 percent) for ESR > 20, and 6 of 8 (75 percent) for ESR > 50. Half the infections were attributed to prior spinal surgery or instrumentation, with the rest attributed to hematogenous spread.

Miron, Khan, Wiesen, et al.[264] evaluated the accuracy of a quantitative bone scan technique, scintigraphy, for diagnosing sacroiliitis in various groups of patients. First, 90 subjects with no history of low back symptoms were evaluated with the test to establish age- and sex-specific normal values for a sacroiliac index. A positive test was defined as a sacroiliac index greater than two standard deviations above the mean for normals. In evaluating patients with low back pain, the test was positive in 50 percent of 18 patients who had signs and symptoms of active sacroiliitis. The test was positive in only 7 percent (1 patient) of 14 patients who had low back pain, but no clinical, x-ray, or CT-scan evidence of sacroiliitis. The authors concluded that this test has a low true positive rate (50 percent), but high true negative rate (93 percent) for diagnosing sacroiliitis.

Esdaile, Rosenthall, Terkeltaub, et al.[262] evaluated Tc-99m bone scan scintigraphy for diagnosing sacroiliitis. Normal values for sacroiliac joint-to-sacrum ratios on scintigraphy were established in 18 controls with no clinical evidence of inflammatory back pain. These ratios were

found abnormally elevated in 66 percent of 12 patients considered to have "possible" ankylosing spondylitis and in 46 percent of 22 patients considered to have "definite" ankylosing spondylitis based on clinical and x-ray findings. At the time of the initial testing, all patients were taking very little or no anti-inflammatory medication. All were then treated with such medication. The S1 joint-to-sacrum ratios significantly decreased after treatment. The authors concluded that this technique is not a useful screening technique to detect early ankylosing spondylitis.

Potential Harms and Costs. The primary potential complications of bone scan involve exposure to ionizing radiation from the radionuclide injected. The total radiation dose to the patient is equivalent to a set of lumbar spine x-rays. This test is contraindicated during pregnancy. The radionuclide may be found in breast milk, and breast feeding must be discontinued for a brief interval after the test. Bone scans are moderately expensive.

Summary of Findings. The bone scan is a moderately sensitive test for detecting suspected tumor, infection, or occult fractures of the vertebrae in patients with low back pain, but not for specifying the diagnosis. A positive bone scan suggesting one of these conditions will usually need to be confirmed using other diagnostic tests or procedures. Bone scan has been shown to be moderately sensitive for detecting metastases to the spine in patients with a previously established diagnosis of cancer who present with acute low back problems. Bone scan also appears to be effective for detecting serious conditions, such as tumor, infection, or fracture, in patients where there is suspicion of these problems based on clinical findings. Bone scan appears to be more accurate than plain x-ray for detecting these conditions. No studies were found comparing the relative accuracy of bone scan versus CT scan or magnetic resonance imaging (MRI) scan for detecting the conditions.

Thermography

Panel findings and recommendations:

Thermography is not recommended for assessing patients with acute low back problems. (Strength of Evidence = C.)

In patients with low back problems, thermography involves measuring small temperature differences between sides of the body and evaluating the patterns on infrared thermographic images of the back and lower extremities. Because thermography is noninvasive and involves no ionizing radiation, the test has been proposed as a physiologic test with clinical utility for documenting the presence or absence of radiculopathy (nerve root compression).

Literature Reviewed. Of 17 articles screened for this topic, only 1 met review criteria for adequate evidence about efficacy.[267] The panel also reviewed a meta-analysis on thermography.[268] Reviewed as well were four articles providing data on thermography in asymptomatic subjects without back problems.[269-272]

Evidence on Efficacy. The one study meeting review criteria[267] evaluated thermography in 107 patients who had sciatica of unspecified duration, 19 of whom went on to have low back surgery, and 28 asymptomatic subjects with no history of back problems and no evidence of disease affecting the lower extremities. All the asymptomatic subjects had temperature differences on thermography of less than 1.9 degreesC in the feet and less than 1.0 degreesC in other parts of the lower limbs. These values were used as the upper limits of normal for evaluating patients with sciatica. Of the 19 patients with sciatica who went on to have surgery, only 53 percent had results on preoperative thermography in agreement with surgical findings.

The most recent meta-analysis[268] reviewed 81 relevant citations and analyzed 28 studies of thermography used for diagnosing lumbar radiculopathy. Articles were graded excellent, good, fair, or poor based on the following criteria: technical quality of the reference test, uniform application of the reference test, independence of interpretations, clinical description, cohort assembly, and sample size. Only excellent and good studies were considered reliable sources of data on diagnostic accuracy. No study was graded excellent, 1 study was graded good, 3 were graded fair, and the remaining 24 were graded poor. Because of the methodological flaws in 27 studies, summary pooled statistics were not reported. The only study considered reliable[267] found no discriminant value for thermography in diagnosing lumbar radiculopathy. True positive and true negative rates were both 48 percent.

The four studies evaluating thermography in persons without back problems found abnormal thermography of the lower limbs in 7 to 81 percent of these asymptomatic subjects. Chafetz, Wexler, and Kaiser,[269] evaluating 15 asymptomatic subjects with no current back pain and no history of back surgery or disability from back pain, found that 40 percent had abnormal thermograms.

Harper, Low, Fealey, et al.[270] evaluated thermography in 37 asymptomatic subjects (carefully screened for no history of back pain, back surgery, or disease or injury affecting the lower extremities) as well as in 55 patients with clinically suspected radiculopathy. All thermograms were interpreted independently by five readers experienced in thermography who were blinded to all clinical data. The different readers interpreted thermograms as probably or definitely abnormal in 56 to 81 percent of the asymptomatic controls.

Perelman, Adler, and Humphreys[271] evaluated thermography in 16 asymptomatic subjects with no low

back complaints and found 25 percent of these subjects to have abnormal thermograms. Tests were considered abnormal if the thermogram had an asymmetric visual pattern, but temperature differences were not measured. So, Aminoff, and Olney[272] evaluated thermography in 30 patients with symptoms of lumbar radiculopathy and in 27 asymptomatic controls. Thermogram readers were blinded to clinical data. Abnormal thermograms, defined as temperature differences between sides greater than three standard deviations from the mean for all asymptomatic subjects, were found in 7 percent of the asymptomatic subjects.

Potential Harms and Costs. No reports of significant risks from thermography were found. Thermography is considered moderately expensive.

Summary of Findings. The one study meeting review criteria found that thermography did not accurately predict either the presence or absence of lumbar nerve root compression found at surgery. In addition, several studies have shown thermography of the lower limbs as abnormal in a substantial proportion of asymptomatic subjects without back problems. Based on the available research evidence, thermography does not appear effective for diagnosing low back problems.

Special Studies: Tests to Provide Anatomic Definition

In addition to x-rays, the imaging studies most generally used to define a possible anatomic cause for evidence of physiologic abnormalities include plain myelography, MRI, CT, CT-myelography, discography, and CT-discography.

Abnormal findings on anatomic studies such as MRI, CT, myelography, and discography may be misleading, however, if they are not corroborated with evidence of

physiologic abnormality from the medical history, physical examination, or physiologic tests. One problem with imaging studies is that in many patients, there is an inability to find any defects. Another problem is the lack of a "gold standard" in determining if an anatomic defect seen on imaging tests is actually the cause of symptoms. Anatomic abnormalities of the lumbar spine, such as degenerative changes and bulging or herniated discs, are found to increase with aging on x-rays and other imaging tests in subjects asymptomatic for low back problems.[273-275]

Several studies stress the importance of not relying too heavily on imaging studies alone for assessment when nerve root compromise is suspected.[30,40,49,50] The anatomic level of imaging study findings must correspond to the side and the level of concern physiologically detected through the history, physical examination, or other physiologic methods.

Plain X-Rays

Panel findings and recommendations:

- Plain x-rays are not recommended for routine evaluation of patients with acute low back problems within the first month of symptoms unless a red flag is noted on clinical examination (such as specified below). (Strength of Evidence = B.)

- Plain x-rays of the lumbar spine are recommended for ruling out fractures in patients with acute low back problems when any of the following red flags are present: recent significant trauma (any age), recent mild trauma (patient over age 50), history of prolonged steroid use, osteoporosis, patient over age 70. (Strength of Evidence = C.)

- Plain x-rays in combination with CBC and ESR may be useful for ruling out tumor or infection in patients with acute low back problems when any of the following red flags are present: prior cancer or recent infection, fever over 100 degreesF, IV drug abuse, prolonged steroid use, low back pain worse with rest, unexplained weight loss. (Strength of Evidence = C.)

- In the presence of red flags, especially for tumor or infection, the use of other imaging studies such as bone scan, CT, or MRI may be clinically indicated even if plain x-rays are negative. (Strength of Evidence = C.)

- The routine use of oblique views on plain lumbar x-rays is not recommended for adults in light of the increased radiation exposure. (Strength of Evidence = B.)

X-ray, or radiography, is the oldest and most widely available modality for imaging the lumbar spine. The most commonly used x-ray views of the lumbar spine, the standard anteroposterior and lateral views, permit assessment of lumbar alignment, comparison of vertebral body and disc space size, assessment of bone density and architecture, and gross evaluation of soft tissue structures. Oblique views of the lumbar spine are used in the detection of unilateral or bilateral spondylolysis. Other special views include sacroiliac views to evaluate possible ankylosing spondylitis. The diagnostic objective of x-rays is to reveal the bony and structural abnormalities associated with back pain.

Literature Reviewed. Of the 128 articles screened for this topic, 20 articles reporting on 18 studies met criteria for review.[26,276-294] Other articles contained information used by the panel, but did not meet article selection criteria.[295,296]

Evidence on Efficacy. Two articles evaluated patients who had less than 3 months of symptoms.[26,278] Two articles involved patients with chronic low back pain.[282,292] Two articles had three separate groups, one asymptomatic, one with patients seen for acute low back problems, and a third comprising patients with chronic low back symptoms.[277,281] The remaining 14 articles (reporting on 13 studies) involved a mix of patients with acute and chronic symptoms or did not report symptom duration.[276,279,280,283-291,293,294]

Hansson, Bigos, Beecher, et al.[281] evaluated the degree of lumbar lordosis seen on x-rays in three groups of age-matched men engaged in heavy labor jobs. They included 200 asymptomatic subjects who had preemployment x-rays, 200 patients seen for acute low back problems, and 200 patients with low back disability longer than 6 months. Films were read by back specialists blinded to all other data. No differences were found between groups in the degree of lordosis noted on x-ray.

Deyo and Diehl[278] evaluated the use of a set of criteria based on medical history questions for selectively ordering x-rays in 621 patients presenting to a hospital emergency room with low back pain (patients with urinary tract symptoms excluded). The 11 criteria, any one of which would prompt an early x-ray, were: (1) age over 50, (2) significant trauma, (3) neuromotor deficits, (4) unexplained weight loss, (5) suspicion of ankylosing spondylitis, (6) drug or alcohol abuse, (7) history of cancer, (8) use of corticosteroids, (9) temperature greater than or equal to 100 F, (10) a return visit for the same problem within 1 month and not improved, and (11) patients seeking compensation for back pain.

X-ray findings were considered therapeutically important if they detected a malignancy or fracture. Of these patients who had x-rays, 227 met one or more of the criteria

for x-ray, and 6.6 percent of these had therapeutically important findings. Another 84 patients had x-rays even though they did not meet any of the criteria. None of this group had therapeutically important x-ray findings. The highest diagnostic yield was in patients over age 50. Of the 119 patients in this group, 11 percent had therapeutically important findings (13 fractures and 2 malignancies). Strict use of the selective criteria would have resulted in x-ray studies in 390 patients.

Deyo and Diehl[26] evaluated 1,975 walk-in patients at a public hospital, their chief complaint back pain, in order to estimate the prevalence of cancer as an underlying cause of back pain. A search of an institutional tumor registry at least 6 months after the index visit identified 13 of these patients whose back pain was attributed to cancer. History findings significantly associated with the diagnosis of cancer were age over 50, prior cancer history, unexplained weight loss, pain lasting more than 1 month, and no improvement following conservative therapy. Laboratory test results significantly associated with cancer were an ESR over 20 and anemia. The authors presented an algorithm for ordering x-rays based on these history and lab test findings that would have resulted in 22 percent of the total group receiving x-rays including all patients who were found to have cancer.

Eleven articles evaluated x-ray findings in patients with low back problems, compared with asymptomatic subjects with no history of back problems. The findings of all of these studies were similar. In general, x-ray findings correlated poorly with low back problems.[276,277,279,281,284,285,287,288,291,292,294]

In all these studies, degenerative changes were noted in some persons with no history of low back problems whereas other persons with back problems showed no degenerative

changes. When groups of subjects of similar age were compared, some studies show an increased prevalence of degenerative changes of the lumbar spine in those who have had back problems, compared to control groups with no history of back problems. Other studies found no significant difference in prevalence of degenerative changes between these groups.

These studies generally support the idea that degenerative changes of the spine, as seen on x-rays or other imaging studies, are not by themselves a cause of back pain. In fact, many authors suggest that degenerative changes of the spine are merely signs of aging of the back. Furthermore, degenerative changes were seen more commonly with increasing age for both those with and those without a history of low back problems.

A possible exception is spondylolisthesis, a forward slippage of a vertebra on the one below it. Two studies showed significantly higher prevalence of spondylolisthesis in patients with low back problems than in asymptomatic individuals. Torgerson and Dotter[294] found spondylolisthesis on x-rays in 4.9 percent of 387 symptomatic low back pain patients, but in only 1.5 percent of 217 asymptomatic subjects. Magora and Schwartz,[290] who evaluated adults currently working, found x-ray evidence of spondylolisthesis in 3.1 percent of 648 subjects with a history of low back pain patients, but in none of 376 subjects who had never had back pain.

Three other studies found no significant difference in prevalence of spondylolisthesis between groups with low back problems and asymptomatic controls. Biering-Sorensen, Hansen, Schroll, et al.[276] evaluated a group of men and women 60 years of age, including 308 with low back pain and 358 asymptomatic controls. This study found an overall prevalence of spondylolisthesis of 2.8 percent, with

no significant difference between the groups of symptomatic patients and controls. Bigos, Hansson, Castillo, et al.[277] found no difference in incidence of spondylolisthesis or other abnormalities in the evaluation of age-matched males whether asymptomatic job applicants, back injury claimants, or disabled patients with greater than 6 months' duration of symptoms. Leboeuf, Kimber, and White[285] found spondylolisthesis on x-rays in 4.9 percent of patients with low back pain and in 5.5 percent of asymptomatic controls. This difference was not significant.

None of the studies reviewed on spondylolisthesis attempted to measure spinal instability, and most did not compare groups in terms of degree of spondylolisthesis. In addition, these studies did not investigate whether there was any therapeutic benefit from determining if a patient has spondylolisthesis (especially in patients with no findings that suggest nerve root compression).

Some authors maintain that adults with severe spondylolisthesis (degree of slip greater than 50 percent or a severe increase in affected joint motion) may require special treatment.[295] However, the degree to which spondylolisthesis and abnormal motion may benefit from special interventions is controversial and beyond the scope of this guideline.

Other reported findings on lumbar x-rays for adult patients with low back problems included: transitional vertebrae (lumbarization or sacralization), spina bifida occulta, increased or decreased lordosis, mild or moderate scoliosis and spondylolysis (an interarticular defect of the posterior vertebral arch), and degenerative joint disease. These findings were reported in similar frequency for 200 subjects without symptoms, for 200 subjects reporting back injury claim, and for 200 subjects disabled more than 6 months. This confirms multiple studies that have questioned

both the use of lumbar radiographs for preemployment screening and the diagnostic significance of many radiologic findings.[277]

Spondylolysis without spondylolisthesis is equally common in persons with and without low back symptoms.[277] Spondylolysis has not been documented to be a cause or precursor of low back problems in adults, and no special treatment is required.

Potential Harms and Costs. Potential harms associated with lumbar spine x-rays are primarily related to the degree of ionizing radiation exposure. Small cumulative doses of ionizing radiation are believed to present minimal or no risks. But lumbar x-rays expose the male and female reproductive organs, especially with routine use of oblique views or repeated exposures. These practices are of questionable value and a particular concern for younger females. Oblique lumbar views approximately double total radiation exposure, compared to standard views, which alone are equivalent to female gonadal radiation of daily chest x-rays for 6, 16, or 96 years, depending upon the machine.[296] Lumbar spine x-rays are seldom indicated during pregnancy.

The cost of a lumbar spine x-ray is low compared to other imaging modalities such as bone scan, CT, or MRI, and x-rays are more readily available.

Summary of Findings. Plain lumbar x-rays have been demonstrated to be useful in helping detect or define spinal fractures, but alone do not rule in or out tumors or infections suspected by other findings (such as when red flags are present). Evidence suggests plain x-rays are rarely useful in evaluating or guiding treatment of adult acute low back pain in the absence of red flags. Plain x-rays are not effective for diagnosing lumbar nerve root impingement of

herniated disc or spinal stenosis, or for ruling out cancer or infection.

The use of lumbar x-rays to screen for spinal degenerative changes, congenital anomalies, spondylolysis, spondylolisthesis, or scoliosis very rarely adds useful clinical information. Only 1 of 2,500 x-rays detects something not suspected on medical history and physical examination that has an impact on patient care. Even in the rare cases where a condition may be clinically significant, the history and physical examination findings (that is, evidence of neurologic dysfunction) should dictate more extensive diagnostic evaluation whether a routine x-ray screening is positive or negative. Oblique lumbar x-rays, usually done to screen for spondylolysis, rarely add useful clinical information in adults, and they double the x-ray dose to the patient. Patients with spondylolisthesis can be safely treated in the same fashion as those with other types of acute low back problems. Thus, x-rays done specifically to screen for the presence of spondylolisthesis are unnecessary in adults during the first 3 months of symptoms.

CT, MRI, Myelography, and CT-Myelography

Panel findings and recommendations:

- In the presence of red flags suggesting cauda equina syndrome or progressive major motor weakness, the prompt use of CT, MRI, myelography, or CT-myelography is recommended. Because these serious problems may require prompt surgical intervention, planning for use of such imaging studies is best done in consultation with a surgeon. (Strength of Evidence = C.)

- CT, MRI, myelography, or CT-myelography and/or consultation with an appropriate specialist is

recommended when clinical findings strongly suggesting tumor, infection, fracture, or other space-occupying lesions of the spine. (Strength of Evidence = C.)

- Routine spinal imaging tests are not generally recommended in the first month of symptoms except in the presence of red flags for serious conditions. After 1 month of symptoms, an imaging test is acceptable when surgery is being considered (or to rule out a suspected serious condition). (Strength of Evidence = B.)

- For patients with acute low back problems who have had prior back surgery, MRI with contrast appears to be the imaging test of choice to distinguish disc herniation from scar tissue associated with prior surgery. (Strength of Evidence = D.)

- CT-myelography and myelography are invasive and have an increased risk of complications. These test are indicated only in special situations for preoperative planning. (Strength of Evidence = D.)

- The following are minimal quality criteria for imaging studies of the lumbar spine (Strength of Evidence = B):

  1. CT and MRI cuts to be made no wider than 0.5 cm and parallel to the vertebral endplates.

  2. MRI scanners to have a magnetic field strength no less than 0.5 T (tesla) and to allow a scanning time adequate for optimal image acquisition.

  3. Myelography and CT-myelography to use water-based contrast media.

4. The technical protocols for these imaging tests to be described on radiologist reports.

Introductory Discussion. The four imaging tests commonly used in assessing the anatomy of the lumbar spinal canal and its contents are plain myelography, CT scan, MRI scan, and CT-myelography. These four tests are discussed as a group because they are used in similar clinical situations, provide similar types of information, and are often compared with each other in research studies. Evaluation is limited by lack of a gold standard for evaluating efficacy. Each test and the type of information it provides are described briefly as follows:

- CT scans use multiple x-ray beams projected at different angles and levels to produce computer-generated axial cross-sectional images of the body.

- MRI scans use magnetic fields to produce computer-generated axial and sagittal cross-sectional images of the body.

- Plain myelography uses plain x-rays, taken after a nonionic water-soluble contrast media is injected into the spinal canal via a lumbar puncture needle, to produce images of the borders and contents of the dural sac.

- CT-myelography uses a CT scan, done after a contrast media has been injected into the dural sac in the same manner as for plain myelography, to produce axial cross-sectional images of the spine that enhance distinction between the dural sac and its surrounding structures.

Significant technological advances have taken place in these imaging modalities over the past several years. Kent,

Haynor, Larson, et al.[297] have suggested technical criteria for the performance of these imaging tests to assure a minimal level of quality. Studies of imaging tests were not considered by the panel if the technical protocols were inadequately described or if the protocols varied significantly among subjects within a study. The panel used the following technical criteria for including studies of individual imaging modalities:

- For myelography, contrast media should be water based, not oil based.

- For CT scans, the axial images (cuts) should be no wider than 0.5 cm and should be parallel to the vertebral endplates.

- For MRI scans, the image quality should be equivalent to or better than scans with magnetic field strength >0.5 T with an adequate scanning technique. Because of significant advances in technology, studies of MRI scans before 1985 were not considered.

The objective of using these imaging tests for patients with acute low back problems is to define medically or surgically remediable anatomic pathological conditions. Therefore, the tests are not done routinely, but are generally used only for patients who present with one of these three clinical situations:

- Back-related leg symptoms and clinically specific detectable nerve root compromise with symptoms severe enough to consider surgical intervention.

- A history of neurogenic claudication and other findings suggesting spinal stenosis with symptoms severe enough to consider surgical intervention.

- Clinical examination findings or other test results suggesting other serious conditions affecting the spine (such as cauda equina syndrome, spinal fracture, infection, tumor, or other mass lesions or defects).

This section assesses the usefulness of the four imaging tests for diagnosing nerve root compromise due to herniated discs or spinal stenosis. The use of imaging tests for evaluating other serious conditions affecting the spine is beyond the scope of this guideline and is not discussed in detail here.

Imaging Tests to Evaluate Suspected Nerve Root Compromise Due to Lumbar Disc Herniation

Literature Reviewed. Overall, 308 articles were screened for the subject of spinal imaging tests. They included 141 for CT scan, 97 for MRI, and 70 for myelography (including CT-myelography). Of the 308, there were 17 articles meeting criteria for review that evaluated lumbar disc herniation as an anatomic cause for suspected nerve root compromise.[20,22,30,35,298-310] Other information used by the panel came from Sackett, Haynes, Guyatt, et al.[311] All of these studies used surgical findings as a reference test.

Evidence on Efficacy. Four articles evaluated plain myelography alone.[20,30,35,301] Three of the four evaluated only patients with no history of prior back surgery.[20,35,301] One included patients with prior back surgery.[30]

In the four studies, lumbar disc herniations were found at surgery in 68 to 96 percent of patients. Studies evaluating the true positive rate and true negative rate of a diagnostic test are generally considered more accurate when the target condition is present in 50 percent of the population studied.[311] Only two of these four studies had prevalence rates for lumbar disc herniation below 80 percent. Aejmelaeus, Hiltunen, Härkönen, et al.[20] studied a group

with a 68-percent prevalence of disc herniation at surgery and calculated the true positive rate of 75 percent and true negative rate of 55 percent for myelography in diagnosing this condition. Herron and Turner,[30] found a disc herniation at surgery 74 percent of the time, and the true positive rate and true negative rate for myelography were 88 percent and 62 percent, respectively. The remaining two articles found a lumbar disc herniation at surgery in 84 to 96 percent of patients. In these studies, myelography was calculated to have a true positive rate of 83 to 94 percent and a true negative rate of 71 to 100 percent for diagnosing lumbar disc herniation. A total of eight studies evaluated CT scan compared with myelography.[22,298-300,304,307-309] Only two of the studies looked at patient groups who had no prior back surgery.[22,307] Two studies included some patients with prior surgery.[304,309] The remaining four studies did not report on this variable.

For diagnosing lumbar disc herniation, all eight studies reported similar ranges of true positive and true negative rates for both tests, and these results were also similar to those from studies of myelography alone. The number of subjects ranged from 37 to 195, and prevalence of lumbar disc herniation found at surgery varied from 55 to 91 percent. The calculated true positive rate of the tests for diagnosing lumbar disc herniation varied from 60 to 91 percent for CT scan and from 65 to 98 percent for myelography. The true negative rate varied from 57 to 100 percent for CT scan and from 43 to 100 percent for myelography. One study allowed estimation of the added diagnostic value of combining information from CT and myelography for the same patient.[309] This study found similar accuracies for CT and myelography when evaluated separately for diagnosing lumbar disc herniation (sensitivities 77 percent and 78 percent, specificities 83 percent and 72 percent). However, when the results of both tests were evaluated together, the true positive and true

negative rates were 91 percent and 56 percent for a positive result defined as either one of the two tests being positive. True positive and true negative rates were 64 percent and 100 percent if a positive result was defined as both tests being positive. This implies that the probability that a true lumbar disc herniation will be detected on imaging is 77 percent if one test is done and 91 percent if both tests are done. This also implies that the probability of an imaging test showing a false-positive lumbar disc herniation is 17 percent or 28 percent if one test is positive, but approaches zero if both tests are positive.

The five remaining articles evaluated multiple imaging tests done in the same patients.[302,303,305,306,310] MRI scan was compared to plain myelography,[310] to CT-myelography,[305] to both plain and CT-myelography,[306] and to CT, plain myelography, and CT-myelography.[303] Another study, also by Jackson, Cain, Jacobs, et al.,[302] evaluated CT, myelography, and CT-myelography and compared them as well to discography and CT-discography. The five studies all found no significant differences between CT, MRI, and CT-myelography in terms of their true positive rates and true negative rates for diagnosing lumbar disc herniation although all these tests were better than plain myelography. Jackson, Cain, Jacobs, et al.[302] found that for diagnosing lumbar disc herniation, CT-discography had a significantly greater true positive rate (92 percent) than CT-myelography (78 percent), plain CT (72 percent), plain myelography (70 percent), or plain discography (31 percent). However, in a subsequent study, Jackson, Cain, Jacobs, et al.[303] recommended MRI over other imaging tests as it is noninvasive and exposes the patient to no ionizing radiation. No differences were found between CT-discography, CT-myelography, CT, or myelography in the true negative rates although all had a significantly higher true negative rate than plain discography.

Imaging Tests to Evaluate Suspected Spinal Stenosis

Literature Reviewed. Lumbar spinal stenosis involves impingement of the cauda equina nerves in the spinal canal, lateral spinal canal, or neural foramina. This is usually a degenerative condition resulting from ligamentous infolding and bony hypertrophy commonly seen in persons over age 60. Spinal stenosis is occasionally developmental, due to congenitally short pedicles, and can affect younger individuals.

One meta-analysis on the accuracy of CT, MRI, and myelography for diagnosing lumbar spinal stenosis in adults was reviewed[297]. Of the 116 articles the authors screened for this meta-analysis, 14 studies met their inclusion criteria for review.[273,275,306,309,312-321]

Evidence on Efficacy. In their meta-analysis, Kent, Haynor, Larson, et al.[297] concluded that estimates of accuracy of the imaging tests for diagnosing spinal stenosis were imprecise and that all 14 studies had methodological flaws (all judged to be of fair or poor quality). However, based on data available, the meta-analysis found CT and MRI of similar accuracy for diagnosing spinal stenosis (true positive and true negative rates approximately 90 percent and 80 percent) and plain myelography with lower accuracy. The authors cautioned that because of bias, estimates of test accuracy obtained by the meta-analysis were likely to be too high.

Spinal Imaging Findings in Asymptomatic Subjects

Literature Reviewed. Six articles were found that evaluated lumbar spinal imaging findings in asymptomatic subjects with no low back symptoms. These studies included one evaluating CT scan,[275] four on [sup]MRI,[273,291,322,323] and one for plain myelography.[274]

Other articles contained information used by the panel, but did not meet article selection criteria.[30,40,49,50]

Evidence on Efficacy. Wiesel, Tsourmas, Feffer, et al.[275] evaluated readings of CT scans for 52 subjects with no history of low back problems, with all scans read independently by three neuroradiologists blinded to other data. For those under age 40, herniated discs were diagnosed in an average of 19. 5 percent of subjects (range for the three readers, 13 to 24 percent). For subjects over age 40, those who had abnormal findings averaged 50 percent (with a range of 30 to 82 percent among the readers). Included were 27 percent of subjects diagnosed with herniated discs, 10 percent with facet joint hypertrophy, and 3 percent with spinal stenosis. Technical quality of this study was considered adequate.

Boden, Davis, Dina, et al.[273] evaluated readings of MRI scans in 67 subjects with no history of back problems. Scans were read by three neuroradiologists blinded to all other data after the scans were randomly mixed with scans of symptomatic patients who had proven back pathology. Of the asymptomatic subjects, 35 were age 20 to 39, 18 were age 40 to 59, and 14 were age 60 and over. The percentages for each of the above age groups were reported respectively by neuroradiologists as: a definite or probable abnormality in 22 percent, 22 percent, and 57 percent; bulging disc in 56 percent, 50 percent, and 79 percent; disc herniation in 21 percent, 22 percent, and 36 percent; degenerative disc in 34 percent, 59 percent, and 93 percent; spinal stenosis in 1 percent, 0 percent, and 21 percent. This study was considered of good technical quality.

Paajanen, Erkintalo, Dahlström, et al.[291] evaluated MRI scans in age-20 male military conscripts including 75 subjects with low back pain and 34 controls with no history of low back problems. Five intervertebral discs, from L1-L2

to L5-S1, were evaluated for each subject. Disc degeneration, indicated by reduced MRI signal intensity for the disc, was found in 57 percent of patients with low back problems and 35 percent of controls. The authors stated that it was unclear if the positive findings in controls represented pathological processes or merely normal aging changes that did not predispose to future low back problems. The technical quality of the MRI scans in this study was considered suboptimal because low field strength MRI (0.02 T) was used.

Powell, Wilson, Szypryt, et al.[322] evaluated the MRI scans in 302 women who had no symptoms of low back problems, but who had the scans done for nonback obstetrical problems. Using reduced MRI signal intensity of the disc as an indication of disc degeneration, the authors found one or more degenerative discs in 34 percent of women age 21 to 30, in 60 percent of women age 31 to 40, and in 95 percent of women by age 70. Bulging discs were found on MRI in 11 percent of 82 pregnant women and 13 percent of 56 women who had never been pregnant (these data not presented by age group).

Weinreb, Wolbarsht, Cohen, et al.[323] evaluated MRI findings in 45 pregnant women age 20 to 39 and in 41 nonpregnant women age 19 to 40 with no current low back symptoms. Three intervertebral disc levels, L3-L4, L4-L5, and L5-S1, were evaluated for all subjects. No significant differences were found between pregnant and nonpregnant women in terms of the percentage with lumbar disc herniation (9 percent compared with 10 percent) or disc bulging without herniation (44 percent in each group). The technical quality of this study was considered suboptimal because testing protocols varied between subjects and low field strength MRI (0.35 T) was used.

Hitselberger and Witten[274] reviewed lumbar myelograms done in 300 patients with no prior history of radiculopathy. The technical quality of this study was considered poor because oil-based contrast media were used, which are less sensitive than more modern techniques. Still, 24 percent had myelographic evidence of lumbar disc herniation, 9.3 percent had spinal stenosis without a history of radicular symptoms (1 of 300 with a complete block of the dye). This study was of limited value because findings were not given by specific age groups, and the age range of subjects was 18 to 76 with a mean age of 51.

Degenerative discs, bulging discs, and even herniated discs are part of the aging process for the spine and may be irrelevant findings; they are seen on imaging tests of the lumbar spine in a significant percentage of subjects with no history of low back problems. Therefore, abnormal imaging findings seen in a patient with acute low back problems may or may not be related to that individual's symptoms. A herniated disc noted on an imaging test is more likely to be associated with a clinically significant nerve root compromise in patients when there are other findings (such as leg pain, positive straight leg raising, neurologic deficits, or a positive electrodiagnostic test) that suggest physiologic nerve root compromise.[30,40,49,50]

Potential Harms and Costs. Factors that may influence the decision on which imaging test to use in diagnosing low back problems include the following: (1) tissue of greatest interest for imaging (CT better for bone, MRI better for imaging neural tissues and bone marrow and for diagnosing tumor or infection); (2) claustrophobia (more of a problem for MRI); (3) obesity (both CT and MRI scanners have a maximum table weight, so that extremely heavy patients may need to have myelography); (4) presence of internal metallic objects such as implanted medical devices, metallic surgical clips, or metallic objects or fragments in the eye,

which can be a major problem for MRI (and sometimes for CT); (5) preference of the consultant and of the patient; (6) availability, cost, and potential side effects of the test.

CT-myelography and myelography have a higher risk of complications than CT or MRI (for example, post-spinal-tap headaches and adverse reactions to contrast media). For CT scan, potential harms include minimal x-ray exposure (including gonadal radiation exposure in females). Amount of exposure (less than two rads) is similar to that from two standard x-ray views of the lumbar spine. For MRI scan, there have been no clearly documented adverse health effects. Long-term effects of magnetic field exposure from MRI are unknown, but this test is generally believed to involve minimal risk. CT scan, MRI scan, CT-myelography, and plain myelography are all considered moderate to expensive in cost.

Summary of Findings. Given the benign natural history of acute low back problems, with 80 to 90 percent of patients expected to improve at 1 month even without treatment, routine spinal imaging tests are not generally necessary during the first month of symptoms except when a red flag (suggesting a medically emergent condition) is noted on medical history and physical examination. After 1 month of symptoms, the use of imaging tests may be appropriate when surgery is being considered for a specific detectable loss of neurologic function or to further evaluate possibly serious spinal pathology in the presence of red flags.

Discography

Panel findings and recommendations:

- Discography is invasive, and its use is not recommended for assessing patients with acute low back pain. Interpretation is equivocal, and complications can be

avoided with other noninvasive techniques. (Strength of Evidence = C.)

- Due to increased potential risks, CT-discography is not recommended over other imaging studies (MRI, CT) for assessing patients with suspected nerve root compression due to lumbar disc hernia. (Strength of Evidence = C.)

Discography involves the injection of a water-soluble imaging material directly into the nucleus pulposus of the disc. Information is then recorded about the amount of dye accepted, the pressure necessary to inject the material, the configuration of the opaque material, and the reproduction of the patient's pain. There are two diagnostic objectives: (1) to evaluate radiographically the extent of disc damage on discogram (sometimes with the addition of CT) and (2) to characterize the pain response (if any) on disc injection to see if it compares with the typical pain of the patient. A symptomatic degenerative disc is considered one that disperses injected contrast in an abnormal pattern, extending to the outer margins of the annulus and possibly into epidural space as well. For many investigators, a painful reaction provoked in the patient that reproduces the patient's usual pain is required to classify the disc as abnormal.

Literature Reviewed. Of the 42 articles evaluated for this topic, only 1 met review criteria for adequate evidence about efficacy.[324] Another article contained information used by the panel, although it did not meet article selection criteria.[325] There were also two articles reviewed that evaluated results of discography in asymptomatic subjects.[326,327]

Evidence on Efficacy. No studies were found that evaluated discography for patients with acute low back

problems. One of the major problems in evaluating the literature on discography is that few studies evaluate discography using an independent reference standard. Instead, many studies either compare discography results with other diagnostic test findings or evaluate discography using pain provocation on disc injection as evidence of discogenic pain, which essentially means using part of a test to validate itself.

In the only study to meet panel review criteria, Colhoun, McCall, Williams, et al.[324] evaluated the results of discography using surgical findings and long-term clinical outcomes as independent reference standards. This study evaluated discography in 195 patients with persistent low back pain (symptom duration not otherwise specified), but with no history of prior back surgery. All patients went on to have back surgery (spinal fusion for 82 percent of patients, laminectomy and/or discectomy for the remaining patients). All patients were followed for 2 to 10 years postoperatively (results not presented separately by type of operation). Patients who had spinal fusion were excluded from the study if the surgery was deemed to be technically unsuccessful (that is, if there was x-ray evidence of pseudoarthrosis at the site of attempted fusion). Treatment success on followup was noted in 89 percent of 137 patients who had positive pain response on discography and abnormal discograms, compared to 52 percent of 25 patients who had negative pain response but abnormal discograms and 50 percent of 12 patients who had a negative pain response and normal discography.

Holt[326] evaluated discograms done in 30 male prison inmate volunteers who had no prior history of low back problems, normal lumbar x-rays, and normal back examinations. Their age range was 21 to 49, average age 26. Discography was attempted at the L3-L4, L4-L5, and L5-S1 disc levels for each subject. Of the 71 successfully performed

discograms, a positive pain response was noted in 37 percent of the discs injected. All of these also had abnormal discograms (showing either degenerative changes or disc rupture). The remaining 63 percent of discs injected had negative pain responses and normal discograms. Holt interpreted these results as showing a 37-percent false-positive rate for discograms. However, in a reevaluation of this study, Walsh, Weinstein, Spratt, et al.[327] noted inconsistencies in Holt's data and recalculated the false-positive rate as either 26 percent or 4 percent depending upon assumptions made.

Walsh, Weinstein, Spratt, et al.[327] evaluated CT-discography done in 7 patients with low back pain and in 10 "asymptomatic" subjects with no history of low back problems. Discography was attempted at three lumbar disc levels for each subject, with a water-soluble nonionic contrast media. Disc injection was videotaped, and the subjects' pain reactions and discograms were later read independently by two orthopedic surgeons and three radiologists blind to all other data. Discography in the patients was considered positive if the discogram was abnormal, if there were two or more videotaped pain behaviors, and if disc injection provoked the patient's typical pain. In asymptomatic subjects, discography was considered positive if the discogram was abnormal and there was significant pain noted on disc injection. Discography was positive in all 7 patients with low back problems (65 percent of the 13 discs successfully injected being abnormal). In the asymptomatic subjects, 50 percent had an abnormal discogram (17 percent of the 30 successful discograms for this group), but none had positive pain response on disc injection. Therefore, none of the asymptomatic subjects was considered to have positive discography (that is, no false- positive tests).

Potential Harms and Costs. Discography is an invasive procedure with risk of complications. Potential complications include disc and disc space infections, disc herniation following disc injection, and significant amounts of ionizing radiation exposure with CT-discography (estimated at 1.5 to 4.0 rads when studying 2-3 discs).[325] Discography is expensive.

Summary of Findings. Although discography seeks to identify internal changes in the disc based on evaluation of a discogram and pain response on disc injection, the disease process is not clear (the internal disc disruption), and how to use the information for acute low back problems is not clear. The main reason put forward for using discography appears to be to determine the levels at which spinal fusion will be successful in patients with persistent low back problems (due to discogenic disease). This assumes the controversial premise of a "painful disc syndrome" which has not yet been adequately documented.

There is no good evidence that discography is useful to promote better treatment outcomes in patients with acute low back problems. Colhoun, McCall, Williams, et al.[324] noted more successful outcomes after back surgery for those with a positive discography, but these were presumably patients with chronic problems (as they had persistent pain). The rationale for using discography is to select patients who would most benefit from spinal fusion. Yet, in the Colhoun article, the predictive value of positive discography in establishing which patients do well after spinal fusion cannot be determined accurately because 18 percent of patients did not have fusions and outcomes were not reported separately for fusions and discectomies. Moreover, the two articles on discography in asymptomatic subjects report a substantial percentage of subjects who had positive discograms although they had never had low back problems.

In summary, there is limited evidence that discography can help select patients who would benefit from spinal fusion and no evidence that it is helpful in patients with acute low back problems. Potential serious risks from discography, including disc infection, have been identified. The use of discography or CT-discography to diagnose herniated discs appears to offer no significant advantage over other imaging methods with less potential risk of harm.

Surgical Information

Surgery is commonly discussed for back symptoms that are unresolved after special studies (Attachment A4). Patients may benefit from general information about the risks and potential outcomes of surgical treatment for different diagnoses.

Surgery for Herniated Disc

Panel findings and recommendations:

- It is recommended that the treating clinician discuss further treatment options, with the patient with sciatica after approximately 1 month of conservative therapy. The clinician should consider referral to a specialist when all of the following conditions are met: (1) sciatica is both severe and disabling, (2) symptoms of sciatica persist without improvement or with progression, and (3) there is clinical evidence of nerve root compromise. (Strength of Evidence = B.)

- Standard discectomy and microdiscectomy are of similar efficacy and appropriate for selected patients with herniated discs and nerve root dysfunction. (Strength of Evidence = B.)

- Chymopapain is an acceptable treatment for such patients, but less efficacious than standard or microdiscectomy. If chymopapain is being considered, testing patients for allergic sensitivity to this substance can reduce incidence of anaphylaxis. (Strength of Evidence = C.)

- Percutaneous discectomy is significantly less efficacious than chymopapain in treating patients with lumbar disc herniation. This and other new methods of lumbar disc surgery are not recommended until they can be proven efficacious in controlled trials. (Strength of Evidence = C.)

- Patients with acute low back pain alone, who have neither suspicious findings for a significant nerve root compression nor any positive red flags, do not need surgical consultation for possible herniated lumbar disc. (Strength of Evidence = D.)

Surgery for herniated discs is invasive and comprises all types of surgical and injection techniques to remove or reduce the size of herniated intervertebral discs that compress nerve roots. Included are standard discectomy, microscopic discectomy, percutaneous discectomy, and chemonucleolysis (chymopapain injection). The therapeutic objective is to relieve pressure on nerve roots and reduce pain and possibly weakness and/or numbness in the lower extremities.

Literature Reviewed. Of 345 articles screened for this topic, 13 reporting on 10 studies met criteria for review.[322,328-339] In addition, a meta-analysis article was reviewed by the panel.[340] Other articles contained information used by the panel, but did not meet article selection criteria.[30,40,49,50,341-345]

Evidence on Efficacy. Three of the studies reviewed were randomized controlled trials (RCTs) that evaluated chymopapain as compared with standard discectomy for patients with symptoms and findings of lumbosacral radiculopathy. Crawshaw, Frazer, Merriam, et al.[328] found that at 1-year followup, 85 percent of those undergoing discectomy had good or excellent results, compared to 44 percent of those receiving chymopapain injections. Both groups had improved leg symptoms, but only the discectomy group had significant improvements in back pain.

Ejeskär, Nachemson, Herberts, et al.[329] found that at 6 months, 56 percent of patients initially receiving chymopapain injections had undergone surgery due to unrelieved symptoms (all of these patients with disc herniation confirmed at surgery). When patients were followed up during the first 6 months before any treatment crossovers occurred, those receiving discectomy reported significantly greater improvement in symptoms than those receiving chymopapain injections.

Van Alphen, Braakman, Bezemer, et al.[336] found that at 1-year followup, physicians rated significantly more of the patients in the discectomy group as having good results from their initial treatment compared with the chymopapain group (85 percent compared with 63 percent). Also, 25 percent of the chymopapain group required subsequent discectomy while only 3 percent of the discectomy group needed a second operation. Open discectomy following prior failed chymopapain injection was successful in 44 percent of the cases.

Another RCT (reported in Fraser;[330] Fraser;[331] and Gogan and Fraser[332]) evaluated chymopapain injections compared with intradiscal saline injections in patients who had sciatica and evidence of a herniated lumbar disc, but who had not

improved after 6 months of conservative therapy. Treatment success rates were significantly better for the chymopapain group than for the saline group at 6-month followup (80 percent compared with 57 percent), at 5-year followup (73 percent compared with 47 percent), and at 10-year followup (80 percent compared with 34 percent). Also, significantly fewer patients required a laminectomy for unrelieved symptoms in the chymopapain group compared with the saline group when followed up at 2 years (20 percent compared with 40 percent) and at 10 years (20 percent compared with 47 percent).

A double-blind RCT by Javid, Nordby, Ford, et al.[333] evaluated chymopapain injection compared with intradiscal saline injection in 108 patients with sciatica who had not improved after at least 6 weeks of conservative treatment including 2 weeks of bed rest. All patients had positive straight leg raising, a neurologic defect on physical examination, and myelogram evidence of a single lumbar disc herniation. At 6 months postinjection, the treatment success rate was significantly better for the chymopapain group compared with the saline injection group (83 percent compared with 42 percent).

Revel, Payan, Vallee, et al.[334] evaluated chymopapain injections compared with percutaneous discectomy in 141 patients with sciatica who did not improve after 1 month of conservative treatment. Overall success rates were significantly better for the chymopapain group than for the percutaneous discectomy group at both 6-month followup (61 percent compared with 44 percent) and 1-year followup (66 percent compared with 37 percent). Also, fewer patients in the chymopapain group required open laminectomy within 1 year due to unrelieved symptoms as compared with the percutaneous discectomy group (7 percent compared with 33 percent).

Only one RCT (reported by Weber[338,339]) compared standard discectomy with conservative (nonsurgical) care. This study looked at 280 patients who consecutively presented to a hospital neurology department with severe sciatica and clinical findings of possible or definite L4-L5 or L5-S1 disc herniation. All patients were initially hospitalized for 2 weeks of conservative treatment including 1 week of strict bed rest. After 2 weeks, 87 patients with possible but indefinite disk hernia who had shown continuous improvement were assigned to continued conservative care, and discectomy was performed for 67 patients who were deemed by their surgeon to have emergent indications for immediate surgery (intolerable pain, suddenly occurring or progressive muscle weakness, or impending bladder or anal sphincter paresis). This left a group of 126 subjects who had continued sciatic symptoms provoked by mild exercise, sitting, or Vasalva maneuver and with myelograms that showed definite disc herniations consistent with their clinical findings of neurologic dysfunction. Patients in this latter group were randomly assigned to receive either standard discectomy or continued conservative treatment.

Of these 126 subjects with definite disc hernia who were randomized, Weber[338,339] found good or fair results in 61 percent of the nonsurgery group and in 90 percent of the discectomy group at 1-year followup. This difference was no longer significant on followup at 4 years (86 percent compared with 89 percent) or 10 years (93 percent compared with 92 percent). At 4-year followup, considerable sciatic pain was still reported by 9 to 10 percent of each group and considerable low back pain by 11 to 12 percent of each group. At 10-year followup, no patients in either group reported these symptoms. During the first year, 26 percent of the nonsurgery group demanded discectomy because of unrelieved sciatic pain. On followup, good or fair results were reported for 82 percent of this group at 4 years and for 100 percent of the group at 10 years.

Tullberg, Isacson, and Weidenhielm[335] evaluated microdiscectomy compared with standard discectomy in a RCT of patients with sciatica who had not improved after 2 months of conservative treatment and had evidence on CT scan of a single-level disc herniation. At 1-year followup, no significant difference was noted between microdiscectomy and standard discectomy groups in terms of patients reporting excellent or good results (86 percent compared with 90 percent), mean postoperative time off work (10.4 weeks compared with 10.1 weeks), or mean improvement in visual analog pain scale ratings over the prior year.

A meta-analysis for herniated lumbar disc surgery by Hoffman, Wheeler, and Deyo[340] found only two RCTs.[336,338,339] This meta-analysis concluded that patients with severe leg symptoms and confirmed lumbar disc herniation experienced faster symptom relief and improved functioning if they underwent standard discectomy rather than conservative treatment. The meta-analysis stated that there was inadequate evidence available to determine the efficacy of microdiscectomy or percutaneous discectomy for treating low back problems. However, percutaneous discectomy was noted to have a higher reoperation rate than standard discectomy. Discectomies were noted to be relatively safe procedures, but reoperations were also reported to be fairly common.

Several studies have emphasized the role psychosocial factors play in influencing the outcome of surgery for herniated disc.[30,40,49,50] In fact, Spengler, Ouellette, Battié, et al.[50] found that psychological factors, especially elevated hysteria or hypochondriasis scales on a Minnesota Multiphasic Personality Inventory (MMPI), were better predictors of surgical outcome than were findings on imaging studies.

Potential Harms and Costs. Reported complications of herniated disc surgery include operative mortality, wound infection, discitis, dural tears, nerve root injuries, thrombophlebitis and pulmonary emboli, meningitis, cauda equina syndrome, psoas hematoma, vascular injuries, and risks associated with transfusions. Hoffman, Wheeler, and Deyo[340] stated that, overall, complications appeared to occur infrequently, but that information on complications was often hard to interpret in the studies reviewed, making determination of rates difficult.

A community-based study in Michigan, which reviewed the hospital discharge records of over 28,000 patients who had a lumbar disc surgery in 1980, reported incidence rates of 0.06 percent for mortality, 0.3 percent for infections treated with intravenous antibiotics, and 0.3 percent for major neurologic complications. A similar study of hospital discharge records in Washington State found an overall mortality incidence of 0.07 percent for spinal surgery.[345]

The reported complications for chymopapain therapy include allergic reactions (some resulting in death), discitis, thrombophlebitis, pulmonary embolus, neurologic injury, vascular injury, and transverse myelitis.[341-344] Skin tests for sensitization before chymopapain injection are reported to significantly reduce the risk of allergic reaction. Transverse myelitis is uncommon, and the risk factors for this are unclear.

Complication rates for discectomy are generally low. Complication rates for chymopapain are also low, but the use of chymopapain has decreased drastically in the United States because of concerns about transverse myelitis and anaphylactic reactions. The use of tests for allergic sensitization to chymopapain before this treatment may reduce the risk of allergic reaction.

Surgery for herniated discs is considered an expensive treatment.

Summary of Findings. Lumbar discectomy may relieve symptoms faster than continued nonsurgical therapy in patients who have severe and disabling leg symptoms (associated with clinical examination findings of definite lumbar nerve root compromise) and who have not improved after 4 to 8 weeks of adequate nonsurgical treatment. However, the evidence also showed that in such nonemergent patients, there appears to be little difference in long-term outcomes at 4 and 10 years between discectomy and conservative care.

There are direct methods of nerve root decompression and indirect methods. The best results from herniated disc surgery were with direct methods of standard discectomy and microscopic discectomy with no significant difference in results noted between these procedures. Studies indicate that the direct method of standard discectomy produces better results than the indirect method of chymopapain. Chymopapain is better than placebo injections of saline or the indirect method of percutaneous discectomy. Rates of initial treatment failure requiring a subsequent surgery are higher for chymopapain than for discectomy.

No studies to date have shown that any of the newer indirect methods of disc surgery, such as indirect automated percutaneous and percutaneous laser discectomy, produce better results than standard discectomy or chymopapain in appropriate patients.

Patient preference does and should play a large role in the surgical decision, but only if adequate information is available about efficacy, risks, and expectations.

Surgery for Spinal Stenosis

Panel findings and recommendations:

- Elderly patients with spinal stenosis who can adequately function in the activities of daily life can be managed with conservative treatments. Surgery for spinal stenosis should not usually be considered in the first 3 months of symptoms. Decisions on treatment should take into account the patient's lifestyle, preference, other medical problems, and risks of surgery. (Strength of Evidence = D.)

- Surgical decisions for patients with spinal stenosis should not be based solely on imaging tests, but should also consider the degree of persistent neurogenic claudication symptoms, associated limitations, and detectable neurologic compromise. (Strength of Evidence = D.)

Spinal stenosis includes any constriction or narrowing of the central spinal canal, the lateral recesses, or foramina resulting in compression of nerve roots and/or the cauda equina. Surgery for spinal stenosis may include various types of surgical techniques, usually including decompressive laminectomy (sometimes combined with discectomy and/or spinal fusion) done to alleviate the symptoms of neural compression.

Spinal stenosis is generally a degenerative condition affecting patients over age 60 and is usually related to a variety of age-related changes in spinal anatomy that combine to cause compression of the cauda equina in the lumbar spinal canal and neuroforamina. These age-related changes may include disc bulges and herniations, thickening of the infolded ligamentum flavum, degeneration of the facet joints and joint capsules,

osteophytes, and occasionally degenerative spondylolisthesis. There are also some younger individuals with severe congenital narrowing of the spinal canal who have spinal stenosis symptoms, but this is uncommon.

The primary symptoms of severe spinal stenosis are neurogenic claudication (leg pain with walking or standing, relieved by sitting or spinal flexion) and occasionally weakness of the legs.

Literature Reviewed. Of the 40 articles screened for this topic, only one met criteria for review. [346] In addition, the panel reviewed an attempted meta-analysis on the topic.[66] Other articles contained information used by the panel, but did not meet article selection criteria.[347,348]

Evidence on Efficacy. No RCTs were found evaluating surgery compared with nonsurgical treatment for spinal stenosis. However, a controlled trial by Herkowitz and Kurz[346] compared decompressive laminectomy done with and without spinal fusion in patients with chronic low back problems (mean symptom duration 3.0 years). None of the patients had improved after adequate conservative treatment, and all had findings consistent with degenerative spondylolisthesis and spinal stenosis on CT, MRI, or myelogram. Internal fixation using metal devices was not done as part of the fusion procedure. Immediately following surgery, the fusion group reported significantly more pain relief in the back and legs than did the nonfusion group. At long-term followup (mean followup time of 3.0 years), the percentage of patients reporting excellent or good outcomes was significantly greater for the fusion group than for the nonfusion group (96 percent compared with 44 percent).

An attempted meta-analysis reviewed 74 studies involving patients who had decompressive laminectomy for lumbar spinal stenosis.[66] The authors of the attempted

meta-analysis found three prospective studies, but no randomized controlled trials comparing surgery with conservative treatment. Therefore, no conclusions could be drawn as to the relative benefits and risks of surgery compared with conservative treatment. One study reported that of 27 unoperated patients with spinal stenosis, 19 remained unchanged, 4 improved, and 4 deteriorated during a followup period of 10 to 103 months with a mean of 49 months.[347] A comparison of these outcomes by Turner, Ersek, Herron, et al.[66] suggested that patients may show more improvement with surgery, but conservative management may be a reasonable alternative.

Of the 74 studies reviewed by Turner, Ersek, Herron, et al.,[66] 31 provided sufficient information to calculate the proportion of patients with good-to-excellent as compared with poor-to-fair outcomes. Criteria for classifying outcomes into categories of excellent, good, fair, and poor varied across studies, making it difficult to combine and compare studies. When results were classified using a standard method for each article, the percentage of patients whose outcomes were classified as good to excellent varied from 26 to 100 percent (mean of 64 percent) for the 31 articles.

Most patients who have surgery for lumbar spinal stenosis have had their symptoms for over a year. It is not a common surgical consideration within the first 3 months of symptoms.[66]

Reoperation rates after spinal stenosis surgery (which were reported in 25 of the articles) ranged from 0 to 21 percent (with a mean of 8 percent). However, the authors speculated that these rates probably underestimated the true reoperation rates because of some followup periods that were very short.

The attempted meta-analysis by Turner, Ersek, Herron, et al.[66] concluded that in patients with severe symptoms from lumbar spinal stenosis, decompressive laminectomy appears to be beneficial for many patients by reducing pain and increasing the ability to function and is probably associated with an acceptably low complication rate.

There are also some data showing that although short-term results from spinal stenosis surgery may be good for most patients, for many patients there may be a progressive deterioration over time. A case series by Katz, Lipson, Larson, et al.,[348] which followed 88 patients over age 55 who had decompressive laminectomy for symptoms of degenerative spinal stenosis, found that 89 percent of patients reported good outcomes (defined as absence of severe pain and no repeat operations) at 1-year followup, but only 57 percent of patients reported good outcomes at 3- to 6-year followups.

Potential Harms and Costs. Complications were also reviewed in the Turner, Ersek, Herron, et al.[66] meta-analysis. Death as a direct result of the surgery was rare, with a mean in-hospital mortality of 0.32 percent. Other reported complications of spinal stenosis surgery included dural tears (mean 0.32 percent), deep infection (mean 5.91 percent), superficial infection (mean 2.3 percent), and deep vein thrombosis (mean 2.78 percent).

The complication rate for spinal stenosis surgery is 10-15 percent, with half the complications being serious or life-threatening problems. These complications can result from the general anesthetic, the spinal problem itself, or coexisting medical problems. The high rate of complications may be because of the older age of this group.

Surgery for spinal stenosis is considered expensive.

Summary of Findings. No RCTs were found comparing surgery with nonsurgical treatment for spinal stenosis. Symptoms of severe and persistent spinal stenosis may either remain the same, gradually worsen, or improve with time. The duration of symptoms for most patients who have surgery for lumbar spinal stenosis exceeds 1 year. This surgery is not commonly considered within the first 3 months of symptoms.

For patients with a history of severe and persistent symptoms of neurogenic claudication who undergo spinal stenosis decompressive laminectomy, the most likely outcomes are less leg pain and improved walking tolerance. However, there is some indication that these results tend to deteriorate over time.

The potential for serious complications from this procedure is considered to be acceptably low, although the rate is higher than for other procedures primarily because this operation is usually done in older individuals.

Spinal Fusion

Panel findings and recommendations:

- In the absence of fracture, dislocation, or complications of tumor or infection, the use of spinal fusion is not recommended for the treatment of low back problems during the first 3 months of symptoms. (Strength of Evidence = C.)

- Spinal fusion should be considered following decompression at a level of increased motion due to degenerative spondylolisthesis. (Strength of Evidence = C.)

Lumbar spinal fusion surgeries use bone grafts, and are sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae. The therapeutic objective of spinal fusion surgery for patients with low back problems is to prevent any movement in the intervertebral spaces between the fused vertebrae, thereby reducing pain and any neurologic deficits. Various theoretical rationales are given for the use of fusion in patients with low back problems. One theory postulates that in cases of significant spinal instability (abnormally increased motion at an intervertebral level), fusion prevents painful compression of the neural structures. Another controversial theory holds that, in some cases, back symptoms arise from the disc itself and fusion relieves symptoms by greatly reducing forces compressing the disc.

Literature Reviewed. Of the 129 articles screened for this topic, 3 met criteria for review.[346,349,350] In addition, a meta-analysis article was reviewed.[351] Other articles contained information used by the panel, but did not meet article selection criteria.[352-356]

Evidence on Efficacy. One RCT evaluated the rate of fusion with and without Knodt rods in patients with a diagnosis of multiple level foraminal stenosis.[349] All patients were treated by wide decompressive laminectomy, foramenotomy and bilateral-lateral fusion from L3 to the sacrum. The rates of fusion, patient-reported functional status, and the lengths of postoperative hospital stays were not significantly different between the two groups.

A controlled trial by Herkowitz and Kurz[346] compared laminectomy with and without fusion in patients with chronic symptoms (mean symptom duration 3.0 years) who did not improve after nonoperative treatment and who had a positive imaging finding (myelogram and either CT or MRI) consistent with degenerative spondylolisthesis and

spinal stenosis. Internal fixation using metal devices was not done as part of the fusion procedure. Following surgery, the fusion group reported significantly greater pain relief in the back and legs than did the nonfusion group. At mean followup of 3.0 years, excellent or good outcome rates were significantly greater for the fusion group than for the nonfusion group (96 percent compared with 44 percent).

The third study meeting review criteria was a nonrandomized trial comparing laminectomy with and without Knodt rod fusion in patients with chronic symptoms, leg pain or neurologic deficit, who did not improve after 3 months of conservative care and who had a positive imaging finding (EMG and myelogram or CT) for a herniated disc.[350] At long-term followup (mean followup time of 4.9 years for the fusion group and 3.7 years for the nonfusion group), the percentages of patients reporting satisfactory results (excellent or good) were not significantly different between the two groups. There are serious design problems with this study, such as the fusion group having a significantly longer mean duration of preoperative symptoms: 5.7 years compared with 1.3 years.

An attempted meta-analysis on this topic[351] found only four nonrandomized studies comparing surgery with and without fusion for herniated disc[350,353,354,356] Three of the four trials reported no significant difference in results between the two groups. One trial did report significantly better results with fusion, but the treatment groups were not comparable. The fusion group had significantly more abnormal findings on x-ray, fewer positive straight leg raising tests, longer duration of pain, and fewer workers' compensation patients.[356]

Potential Harms and Costs. Turner, Ersek, Herron, et al.[351] indicated that complications are frequent with lumbar spinal fusions. Based on a review of a large case series, the

mean rates for the most common reported complications were 7.3 percent for instrumentation failure and 10.8 percent for bone graft donor site pain. The mean rates for other complications were 0.2 percent for in-hospital mortality, 1.5 percent for deep infection, 1.6 percent for superficial infection, 3.7 percent for deep vein thrombosis/ thrombophlebitis, 2.2 percent for pulmonary embolus, 2.8 percent for neural injury, 2.0 percent for graft extrusion, and 8.7 percent for other complications. Spinal fusion is also considered an expensive procedure.

Summary of Findings. There appears to be no good evidence from controlled trials that spinal fusion alone is effective for treatment of any type of acute low back problems in the absence of spinal fractures or dislocation. In the opinion of the panel, there may be two conditions where spinal fusion could be effective. The first is in cases of combined degenerative spondylolisthesis, stenosis, and radiculopathy where patients have decompressive laminectomy for spinal stenosis symptoms. The second situation is in some young patients (generally under age 30) with significant spondylolisthesis and severe leg pain who may receive some benefit from stabilization procedures, although this has not been proven in controlled trials.

Although the usual reasons stated for doing spinal fusion for degenerative problems are instability of the spine and disc disease, there is lack of scientific agreement on how to define spinal instability. Spondylolisthesis is often implicated as a cause of instability, but it may or may not have any detectable abnormal motion and the extent to which this contributes to low back symptoms is controversial. Moreover, there is no good evidence that patients who undergo fusion will return to their prior functional level. It appears that fusion is not commonly considered for adults within the first 3 months of symptoms except for fracture or dislocation.[346,350]

Assessment of Psychosocial Factors

Panel findings and recommendations:

- Social, economic, and psychological factors can significantly alter a patient's response to back symptoms and to the treatment of those symptoms. (Strength of Evidence = D.)

- In a patient with acute low back symptoms and no evidence of serious underlying spinal pathology, the inability to regain tolerance of required activities may indicate that unrealistic expectations or psychosocial factors need to be explored before considering referral for a more extensive evaluation or treatment program. (Strength of Evidence = D.)

Social, economic, and psychological factors have been reported to be more important than physical factors in affecting the symptoms, response to treatment, and long-term outcomes of patients with chronic low back problems.[357] There are indications that such nonphysical factors may affect clinical outcomes for patients with acute low back symptoms (Attachment A5). A heightened awareness among clinicians to the way such factors may affect a patient's response to symptoms and treatment is therefore warranted.

Literature Reviewed

None of the articles screened about psychosocial factors in the assessment and treatment of low back problems were controlled trials and therefore do not meet panel review criteria for adequate evidence about efficacy. Five articles, however, that included prospective cohort studies contained information considered useful to the panel.[23,50,358-360]

Evidence of Efficacy

One large prospective study[358] of asymptomatic individuals at a worksite found premorbid nonphysical factors (i.e., measures of low work satisfaction and poor work performance reports) to be the best predictors of individuals reporting back problems at work. In a second study,[23] psychological variables measured early in the course of an acute low back episode did not predict outcome, although other nonphysical factors, such as educational level and perception of both job characteristics and "fault" concerning the back problem, were strong predictors of outcome. A population-based study[359] also suggested that psychosocial issues affect how individuals with low back symptoms make decisions about working.

Several studies have detected a strong correlation between the outcome of lumbar spine surgery and the preoperative psychological status of the patient.[50,360]

Summary of Findings

The panel found evidence that psychological, social, and economic (nonphysical) factors can alter the response to symptoms and to treatment (including surgery) among patients with acute low back problems. While such nonphysical factors have been shown to affect outcomes, specific and effective interventions to address these factors and alter patient outcomes have yet to be defined. No studies that directly evaluated interventions aimed at psychosocial factors among patients with acute low back problems were found.

Given such limited information, the panel was55555 unable to recommend specific assessment tools or interventions focusing on psychosocial factors potentially important for patients with acute low back problems.

Recognizing the impact such nonphysical issues can have on outcomes, however, the panel recommended that clinicians be aware of these factors, especially in patients whose recovery of activity tolerance following an acute low back problem seems delayed. Further research is needed to define specific methods of detecting nonphysical factors as well as interventions that might improve outcomes for those patients slow to recover from acute low back problems.

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Glossary

Acute low back problem. Activity limitation(s) due to low back symptoms (back pain or back-related leg pain) present less than 3 months.

Back school. A structured educational program, usually in a group setting, designed to inform patients about low back problems.

Biofeedback. The use of auditory and visual signals reflecting a patient's muscular activity to allow the patient to facilitate or extinguish this muscle action. In patients with low back pain, the objective is to reduce pain by reducing muscle tension.

Cauda equina syndrome. Compression (usually due to the extrinsic pressure of a massive, centrally herniated disc) on a sheaf of nerve roots from the lower cord segments, often resulting in bilateral motor weakness of the lower extremities, saddle anesthesia, and urine retention or incontinence from loss of sphincter function.

Chemonucleolysis. The injection of a proteolytic enzyme (e.g., chymopapain) into the herniated nucleus pulposus of a disc.

CT-myelography. Computerized tomography done after contrast media has been injected into the dural sac.

Diathermy. Therapeutic elevation of the temperature of deep tissues by means of high frequency shortwave or microwaves.

Discography. The injection of a water-soluble imaging material directly into the nucleus pulposus of a disc to

assess the extent of disc damage and characterize the pain response.

Discectomy. The surgical removal of all or part of a herniated intervertebral disc compressing a nerve root. When microscopic or visually aided surgical techniques are used, this procedure is referred to as microdiscectomy. The procedure can also be done through a small incision using indirect visualization (percutaneous discectomy).

Electromyography (EMG). An examination of the electrical activity of a motor unit, useful in determining the site of injury in a peripheral nerve and in detecting spinal nerve root lesions as well as primary muscle diseases. Needle EMG involves the insertion of needle electrodes into muscle; surface EMG uses surface electrodes instead of needle insertion.

Ergonomics. The study of the proper and efficient use of the body in work and recreation, including the design and operations of machines and the physical environment.

F-wave tests. The use of electrodiagnostic equipment to measure motor conduction through nerve roots, most frequently to assess proximal neuropathies.

Facet joints. Synovial joints formed by the facets on the articular processes of contiguous vertebrae.

H-reflex tests. The use of electrodiagnostic equipment to measure sensory conduction of a stimulus through nerve roots that then evoke a motor reflex, commonly employed to assess S1 radiculopathy.

Herniated disc. Herniation of the central gelatinous material (nucleus pulposus) of an intervertebral disc through its fibrous outer covering (annulus fibrosis).

Nerve conduction studies. Tests of peripheral nerves performed by stimulating the nerve at one point and measuring the action potential either at another point along the nerve (sensory conduction) or of the muscle innervated by the nerve (motor conduction).

Neurogenic claudication. Symptoms of leg pain (and occasionally weakness) on walking or standing, relieved by sitting or spinal flexion, related to neural compression, usually spinal stenosis.

Pain drawings. Drawings by patients depicting the severity, type, and location of their pain as a technique for assessing psychological involvement in the pain complaints.

Radiculopathy. Dysfunction of a nerve root often caused by compression of the root. Pain, sensory impairment, weakness or depression of deep tendon reflexes may be noticed in the distribution of nerves derived from the involved nerve root.

Saddle anesthesia. Loss of sensation in the skin over the perineum indicative of dysfunction of sacral nerve roots.

Sciatica. Pain radiating down the leg(s) below the knee along the distribution of the sciatic nerve, usually related to mechanical pressure and/or inflammation of lumbosacral nerve roots.

Sensory evoked potentials (SEP). The use of electrical stimuli applied to specific nerves or dermatomes to assess the normalcy of nerve responses.

Spinal manipulation. Manual therapy for symptomatic relief and functional improvement of the back in which loads are applied to the spine using short or long lever methods. The selected spinal joint is moved to its end range

of voluntary motion, followed by application of an impulse load.

Spinal stenosis. A narrowing of the spinal canal that may produce a bony constriction of the cauda equina and the emerging nerve roots.

Spondylolisthesis. Forward subluxation of the body of a lumbar vertebra on the vertebra below.

Spondylolysis. A fracture or cleft in the vertebral body, often through the posterior vertebral arch, loosening its normally firm attachment to contiguous vertebrae.

Straight leg raising (SLR). A procedure of stretching the sciatic nerve to see if radicular symptomatology is reproduced. Each hip is alternately flexed with the knee extended; the extent to which each leg can be lifted is noted. Reproduction of the patient's sciatica when the unaffected leg is lifted is evidence of a positive "crossed" straight leg raising test.

Thermography. A procedure that images the infrared radiation (heat) emitted from body surfaces. In patients with low back problems, thermographic image patterns of the back and lower extremities are measured.

Transcutaneous electrical nerve stimulation (TENS). A small battery-operated device, worn by the patient, which provides continuous electrical pulses via surface electrodes with the goal of providing symptomatic relief by modifying pain perception.

Traction. When used for low back problems, intermittent or continuous force is applied along the axis of the spine in an attempt to elongate the spine. The type most commonly used for low back problems is pelvic traction in which a

girdle around the patient's pelvis is attached to weights hung at the foot of the bed.

Trigger point. A well localized point of tenderness. In low back problems, these points are usually located in the paravertebral areas.

Visual analog scales. A visual means by which a patient can quantify pain. The patient marks a point corresponding to the intensity of his pain on a line, one end of which represents no pain and the other end, severe, incapacitating pain.

Contributors

Acute Low Back Problems Guideline Panel

Stanley J. Bigos, MD, *Chair*
Orthopedic Surgery

Dr. Bigos is Professor of Orthopedic Surgery and Environmental Health at the University of Washington School of Medicine and founder and director of the Spine Resource Clinic in Seattle. He is the author of numerous articles and book chapters focusing on back problems in industry and the management of back pain. He has contributed to a new method of spine evaluation included in the American Medical Association's "Guidelines to Evaluate Permanent Impairment, 4th edition, 1993" and also serves as Consultant to the Clinical Standards Advisory Group of the British Department of Health. Among his many honors, Dr. Bigos received from the American Academy of Orthopaedic Surgeons in 1991 the Kappa Delta Award for Orthopedic Excellence for his sentinel work on industrial back problems.

Rev. O. Richard Bowyer
Consumer

Rev. Bowyer has experienced low back pain for many years. He is campus minister at Fairmont State College, West Virginia, and also serves on the Board of Directors and Quality Assurance Committee of the Monongahela Valley Association of Health Centers. From 1981-1993 he was a consumer member of the West Virginia Board of Medicine and served as chairperson of the Board's Complaints Committee.

G. Richard Braen, MD
Emergency Medicine

Dr. Braen is a practicing emergency physician at Buffalo General Hospital and Professor and Chairman of the Department of Emergency Medicine at State University of New York, Buffalo. Certified by both the American Board of Emergency Medicine and the American Board of Internal Medicine, he has served on several guideline panels established by the American College of Emergency Physicians. He is currently President of the American Board of Emergency Medicine.

Kathleen Brown, PhD, RN
Occupational Health Nursing

Dr. Brown is Professor in the School of Nursing of the University of Alabama at Birmingham and director of Occupational Health Nursing for the NIOSH-funded Educational Resource Center for Occupational Health and Safety. Her research and publications have focused on the cost-effectiveness of back school interventions and the effect of back school education and exercise on back-injured municipal workers. She is principal investigator of an NIH-funded study of worksite education and exercise to prevent back injuries.

Richard Deyo, MD, MPH
Internal Medicine

Dr. Deyo, a general internist, is Professor in the Departments of Medicine and Health Services at the University of Washington School of Medicine, and staff physician at the Seattle Veterans Affairs Medical Center. He is principal investigator of the low back pain Patient Outcome Research Team (PORT) and has published widely on the diagnosis and treatment of low back problems in primary care and on the measurement of quality-of-life and outcomes of surgery for patients with back pain.

Scott Haldeman, DC, MD, PhD
Neurology/Chiropractic

Dr. Haldeman is trained in chiropractic and is board certified in neurology, neurophysiology and electrodiagnosis. He is an Associate Clinical Professor of Neurology at the University of California, Irvine, and an Adjunct Professor at Los Angeles Chiropractic College. He is past president of the North American Spine Society and the North American Academy of Manipulative Medicine and has published widely in the fields of electrodiagnosis, spinal manipulation, and back pain.

John L. Hart, DO
Rehabilitation Medicine

Dr. Hart serves as Director of Outpatient Physical Medicine and Rehabilitation at Still Regional Medical Center in Columbia, Missouri. His research interests include nonoperative treatment of herniated discs and the relationship of employee/employer interactions to the symptoms of low back pain.

Ernest W. Johnson, MD
Physical Medicine/Rehabilitation

Dr. Johnson served for 25 years as Chair of the Department of Physical Medicine and Rehabilitation at the Ohio State University College of Medicine before assuming his present position as Professor and Associate Dean for External Affairs. He is past president of the American Academy of Physical Medicine and Rehabilitation, the Association of Academic Physiatrists, and the American Association of Electrodiagnostic Medicine. The author of numerous articles on electromyography, he serves as Chair of the American Board of Electrodiagnostic Medicine.

Robert Keller, MD
Orthopedic Surgery

Dr. Keller serves as Executive Director of the Maine Medical Assessment Foundation and is a member of the Council on Health Policy and Practice of the American Academy of Orthopaedic Surgeons. He is co-investigator of the Patient Outcomes Research Team (PORT) evaluating low back pain and surgical outcomes and has published on the subject of small area analysis and physician behavior change. A past president of the Maine Medical Association, he is an Adjunct Professor of Community and Family Medicine and Surgery in the Dartmouth Medical School.

Daniel Kido, MD, FACR
Radiology

Dr. Kido is a Professor of Radiology and Director of the Neuroradiology Section of the Mallinckrodt Institute of Washington University School of Medicine in St. Louis, Missouri. His research and publications have focused on the assessment of imaging techniques to evaluate low back pain, including MRI, CT, and myelography. He has also

compared invasive and noninvasive imaging procedures of the low back, documenting frequency of complications.

Matthew H. Liang, MD, MPH
Internal Medicine/Rheumatology

Dr. Liang is an Associate Professor in the Departments of Medicine and Rheumatology at Harvard Medical School. He also serves as medical director of rehabilitation services at the Brigham and Women's Hospital in Boston. His major research interests include outcome assessment of low back problems, cost-effectiveness of diagnostic procedures, and outcomes of spinal stenosis surgery.

Roger M. Nelson, PT, PhD
Physical Therapy

Dr. Nelson is Professor and Chairman of the Department of Physical Therapy at the Thomas Jefferson University College of Allied Health Sciences. His clinical interests include electromyography and measurements of outcome and satisfaction of low back pain patients. He is a contributor to the National Institute of Occupational Safety and Health (NIOSH) Low Back Atlas on the subject of tests and measures for the assessment of low back pain.

Margareta Nordin, RPT, DrSci
Orthopedic Research

Dr. Nordin is Research Associate Professor and Director of the Occupational and Industrial Orthopaedic Center of the Hospital for Joint Diseases in New York City. Her primary research interest is the prevention of chronicity among patients with low back pain. She has published extensively on the biomechanics, ergonomics, and early care of low back pain.

Bernice D. Owen, PhD, RN
Community Health Nursing

Dr. Owen is a Professor in the School of Nursing of the Center for Health Sciences, University of Wisconsin, Madison. Her work as a teacher and researcher has focused on back stress among health care personnel and the reduction of physical demands on the back in occupational settings. She currently serves as a consultant on back injury reduction programs to hospitals, long-term care facilities, and home care agencies.

Malcolm H. Pope, DrMedSc, PhD
Orthopedic Research/Biomedical Engineering

Dr. Pope is Professor of Biomedical Engineering at the University of Iowa and serves as Director of the Iowa Spine Research Center. Before coming to Iowa, he was Director of Orthopaedic Research at the University of Vermont. His research and numerous publications have focused on the biomechanics of low back pain, ergonomics, and the primary and secondary prevention of low back problems.

Richard K. Schwartz, MS, OTR, FSR
Occupational Therapy

Mr. Schwartz has treated work-related injuries since 1972. He is currently in private practice as an occupational therapy consultant on injury prevention, ergonomics, and early return-to-work programs. Before 1992 he was Associate Professor and Chairman of Occupational Therapy at the University of Texas Health Science Center at San Antonio.

Donald H. Stewart, Jr., MD
Neurosurgery

Until his retirement in 1993, Dr. Stewart was in private practice as a neurosurgeon in Syracuse, New York. He also served as Clinical Assistant Professor of Neurosurgery at the State University of New York, Syracuse. He has published widely on medical economics and medical liability.

Jeff Susman, MD
Family Practice

Dr. Susman is Associate Professor, Director of Primary Care, and Vice Chairperson of the Department of Family Practice at the University of Nebraska Medical Center. A member of the American Academy of Family Physicians' Task Force on Clinical Policies, he is interested in clinical decisionmaking by physicians and the effects of guidelines on health provider behavior.

John J. Triano, MA, DC
Chiropractic

Dr. Triano is a staff chiropractic physician and a clinical research scientist at the Texas Back Institute in Plano, Texas. He coordinates the work of interdisciplinary teams in the rehabilitation of patients with spinal pain and conducts research on spine biomechanics and the outcomes of patients treated for spinal problems. He has served as a consultant to the U.S. Department of Labor and NIOSH training programs and is a Professor at the National College of Chiropractic, Lombard, Illinois.

Lucius C. Tripp, MD, MPH, FACPM
Industrial Medicine/Neurosurgery

Dr. Tripp, a neurosurgeon, is board certified in Occupational Medicine and Addiction Medicine. He serves as Medical Director of the General Motors-Henry Ford Hospital Rehabilitation Center in Warren, Michigan, and is actively involved in research on the prevention of back injury and restoration of function in patients with back pain. He is a member of the Board of Directors of the American College of Occupational and Environmental Medicine.

Dennis C. Turk, PhD
Psychology

Dr. Turk is a Professor in the Departments of Psychiatry and Anesthesiology at the University of Pittsburgh School of Medicine. He serves as Director of the University's Pain Evaluation and Treatment Institute, a large interdisciplinary facility that annually evaluates and treats over 1,500 new patients, the majority of whom have back pain. His current research is directed toward examination of the role of psychological factors in back pain and the accompanying disability.

Clark Watts, MD, JD
Neurosurgery

Dr. Watts is a Professor of Neurosurgery at the University of Texas Health Science Center at San Antonio. As editor of Neurosurgery from 1982-1987, he was responsible for evaluating and publishing research on the care of low back problems. His own research has focused on the nature of discogenic pain and the clinical management (operative and nonoperative) of low back problems.

James N. Weinstein, DO
Orthopedic Surgery

Dr. Weinstein is a Professor in the Departments of Orthopaedic Surgery and Biomedical Engineering and is Director of the Spine Diagnostic and Treatment Center at the University of Iowa Hospitals and Clinics. His research has focused on the basic mechanisms of pain and aging, the diagnosis and treatment of spinal tumors, and the evaluation of outcomes for patients with low back pain. He is currently Editor-in-Chief of the journal Spine.

Other Contributors

Project Directors

John P. Holland, MD, MPH
University of Washington
Seattle, Washington

John S. Webster, MD
Naval Regional Medical Center
San Diego, California

Consultants

Michele C. Battie, PhD, PT
Orthopedic Research
University of Washington
Seattle, Washington

Claire Bombardier, MD, FRCP
Rheumatology/Clinical Epidemiology
University of Toronto
Toronto, Ontario, Canada

Nortin M. Hadler, MD
Rheumatology
University of North Carolina
Chapel Hill, North Carolina

Alf L. Nachemson, MD, PhD
Orthopaedic Surgery
Göteborg University
Göteborg, Sweden

Gordon Waddell, MD
Orthopaedic Surgery
Western Infirmary
Glasgow, Scotland

Methodologists

David L. Schriger, MD, MPH
UCLA Medical School
Los Angeles, California

Paul G. Shekelle, MD, MPH
Department of Veterans Affairs Medical Center
West Los Angeles, California

Panel Staff

Mary M. Webster, MA
Seattle, Washington

Laura Novell
St. Louis, Missouri

Keld Vaegter, MD
Ralix, Sweden

AHCPR Staff

David Lanier, MD, MFA
Project Officer

Randie A. Siegel
Managing Editor

Harriet V. Bennett
Karen Carp
Public Affairs Specialists

Peer Reviewers[1]

Lucien Abenhaim, MD, MSc, ScD
McGill University
Montreal, Quebec, Canada

Gad Alon, PhD, PT
University of Maryland
Department of Physical Therapy
Baltimore, Maryland

Michael Andary, MD
Michigan State University
College of Osteopathic Medicine
East Lansing, Michigan

Gunnar B.J. Andersson, MD, PhD
Rush-Presbyterian-St. Luke's Medical Center
Chicago, Illinois

---

[1] Being listed in this section does not necessarily imply endorsement of the guideline products

Howard A. Balduc, DC
American Chiropractic Association
Arlington, Virginia

Judith C. Bautch, PhD, RN, CS
University of Wisconsin School of Nursing
Madison, Wisconsin

James R. Bean, MD
Neurosurgical Associates
Lexington, Kentucky

Alfred O. Berg, MD, MPH
University of Washington
Seattle, Washington

Stephen Blood, DO
American Academy of Osteopathy
Indianapolis, Indiana

Wilbur J. Boike, MD
Center for Comprehensive Back Care
Flint, Michigan

Richard H. Borman, MD
University of California
San Diego, California

Albert M. Brady, MD
Harris Methodist Health System
Fort Worth, Texas

Phillip O. Bridenbaugh, MD
University of Cincinnati Medical Center
Cincinnati, Ohio

Jerry M. Calkins, PhD, MD
University of Arizona Department of Anesthesiology
Phoenix, Arizona

J. David Cassidy, DC, PhD
Royal University Hospital Department of Orthopaedics
Saskatoon, Saskatchewan, Canada

C. Richard Chapman, PhD
University of Washington Department of Anesthesiology
Seattle, Washington

Steven G. Charapata, MD
Pain Management Associates
Kansas City, Missouri

Joy White Danches, MOT, OTR
Visionary Management, Inc.
Dallas, Texas

Marsha Courville Davis, MSN, RN, CRRN
Association of Rehabilitation Nurses
Jackson, Mississippi

Douglas E. DeGood, PhD
University of Virginia Health Sciences Center
Charlottesville, Virginia

Anthony Delitto, PT, PhD
University of Pittsburgh
Pittsburgh, Pennsylvania

Mark A. Doyne, MD, FACPE
Texas Back Institute
Dallas, Texas

Daniel A. Dyrek, MS, PT
Massachusetts General Hospital
Boston, Massachusetts

Frank Eismont, MD
University of Miami School of Medicine
Miami, Florida

Maury R. Ellenberg, MD, FACP
Wayne State University School of Medicine
Detroit, Michigan

Julia Faucett, RN, PhD
University of California
San Francisco, California

Morris A. Fisher, MD
Loyola University Stritch School of Medicine
Chicago, Illinois

Gary M. Franklin, MD, MPH
University of Washington Occupational Epidemiology
Seattle, Washington

Todd D. Gastaldo, DC
Private Chiropractic Research
Sunnyvale, California

Sharon J. Gates
The Graduate Hospital
Philadelphia, Pennsylvania

Michael Goertz, MD, MPH
Airport Medical Clinic
Minneapolis, Minnesota

Michael K. Greenberg, MD
Uniformed Services University of the Health Sciences
Bethesda, Maryland

J. Eric Griffiths, DC
Wheat Ridge Chiropractic Center
Denver, Colorado

Daniel T. Hansen, DC, FICC
Private Practice of Chiropractic
Olympia, Washington

Dennis L. Hart, PhD, PT
Rehability Corporation
Falls Church, Virginia

Jodie K. Haselkorn, MD, MPH
Veterans Affairs Medical Center
Seattle, Washington

Stanley A. Herring, MD
Puget Sound Sports and Spine Physicians
Seattle, Washington

Paul D. Howard, PhD, PT
Thomas Jefferson University
Philadelphia, Pennsylvania

Thomas E. Hyde, DC, CCSP
American Chiropractic Association Sports Council
North Miami Beach, Florida

Susan J. Isernhagen, PT
Isernhagen & Associates, Inc.
Duluth, Minnesota

Manucher J. Javid, MD
University of Wisconsin
Department of Neurosurgery
Madison, Wisconsin

John H. Juhl, DO
American Academy of Osteopathy
New York, New York

Neil Kahanovitz, MD
Anderson Clinic
Arlington, Virginia

Robert D. Kerns, PhD
West Haven VA Medical Center
Yale University
West Haven, Connecticut

Myron M. LaBan, MD, FACP
William Beaumont Hospital Department of Physical Medicine and Rehabilitation
Royal Oak, Michigan

Ruth A. Larkin, RN
North Colorado Medical Center
Greeley, Colorado

Casey K. Lee, MD
New Jersey Medical School Department of Orthopaedics
Newark, New Jersey

Daniel Lessard
Back Health Medical Centers
Seattle, Washington

Stephen M. Levin, MD
American Academy of Orthopaedic Medicine
Vienna, Virginia

Philipp M. Lippe, MD, FACS, FACPM
American Academy of Pain Medicine
Skokie, Illinois

Michael D. Lockshin, MD
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institutes of Health
Bethesda, Maryland

John D. Loeser, MD
University of Washington
Seattle, Washington

Don M. Long, MD, PhD
Johns Hopkins University School of Medicine
Baltimore, Maryland

Sally L. Lusk, PhD, RN, FAAN
University of Michigan School of Nursing
Ann Arbor, Michigan

Norman J. Marcus, MD
New York Pain Treatment Program
Lenox Hill Hospital
New York, New York

Stephen C. Marini, MS, DC, PhD
Pennsylvania College of Chiropractic
Philadelphia, Pennsylvania

Tom G. Mayer, MD
Southwestern Medical School Department of Orthopedics
Dallas, Texas

George B. McClelland, DC
Foundation for Chiropractic Education and Research
Arlington, Virginia

William A. McIlwain, MD, FACS
Bristol Regional Medical Center
Bristol, Tennessee

William C. Meeker, DC, MPH
Palmer College of Chiropractic-West
San Jose, California

Christine Miaskowski, RN, PhD
University of California
San Francisco, California

Edward H. Mills, MD
U.S. Department of Labor
Seattle, Washington

Michael Mittelmann, MD
Aetna Life and Casualty
Hartford, Connecticut

Vert Mooney, MD
University of California
San Diego, California

Mary T. Muffroid, PhD, PT
University of Vermont
Burlington, Vermont

Albert M. Murtland, MD
Guthrie Clinic
Sayre, Pennsylvania

David E. Nestor, MS, PT, ECS
U.S. Public Health Service
Rochester, Minnesota

E.J. Nordby, MD
University of Wisconsin Medical School
Madison, Wisconsin

Jane E. Parker-Conrad, PhD, RN
Walters State College
Morristown, Tennessee

Richard Payne, MD
University of Texas M.D. Anderson Cancer Center
Houston, Texas

Reed B. Phillips, DC, PhD
Los Angeles College of Chiropractic
Whittier, California

William R. Phillips, MD, MPH
University of Washington
Seattle, Washington

Vern Putz-Anderson, PhD
National Institute for Occupational Safety and Health
Cincinnati, Ohio

Jan K. Richardson, PT, PhD
Slippery Rock University School of Physical Therapy
Pittsburgh, Pennsylvania

Hubert L. Rosomoff, MD, DMedSc
University of Miami School of Medicine
Department of Neurological Surgery
Miami, Florida

Renee Steele Rosomoff, RN, MBA, CRC
University of Miami Comprehensive Pain and Rehabilitation Center
Miami Beach, Florida

Michel Rossignol, MD, FRCPC
McGill University
Montreal, Quebec, Canada

Donald Sheffel, MD
Memorial Hospital Division of Neurosurgery
Hollywood, Florida

Dennis Shubert, MD, PhD
Neurosurgical Associates
Bangor, Maine

Stover H. Snook, PhD
Liberty Mutual Insurance Company
Hopkinton, Massachusetts

Jody L. Snow, PT
Sacred Heart Medical Center
The Rehabilitation Center
Spokane, Washington

Dan M. Spengler, MD
Vanderbilt University Medical Center Department of Orthopaedics and Rehabilitation
Nashville, Tennessee

Richard L. Stieg, MD
University of Colorado Health Sciences Center Department of Neurology
Denver, Colorado

Rand S. Swenson, DC, MD, PhD
Dartmouth Medical School
Hanover, New Hampshire

Robert L. Swezey, MD, FACP, FACR
Arthritis & Back Pain Center
Santa Monica, California

Peter J. Vicente, PhD
Good Samaritan Hospital Pain Rehabilitation Center
Cincinnati, Ohio

Nicholas E. Walsh, MD
University of Texas Health Science Center
San Antonio, Texas

Barbara S. Webster, RPT, PA-C
American Academy of Physician Assistants
Alexandria, Virginia

Debra Weiner, MD
Duke University Medical Center
Durham, North Carolina

Arthur H. White, MD
San Francisco Spine Institute
San Francisco, California

John W. Wickenden, MD
Penobscot Bay Medical Center
Rockport, Maine

Sam W. Wiesel, MD
Georgetown University Medical Center Department of Orthopaedics
Washington, DC

Arthur Winter, MD, FICS
University of Medicine and Dentistry of New Jersey
New Jersey Neurological Institute
Livingston, New Jersey

Hansen A. Yuan, MD
State University of New York
Syracuse, New York

Pilot Reviewers[1]

Douglas A. Benner, MD
Kaiser Permanente
Oakland, California

James E. Blessman, Jr., MD, MPH
Wayne State University
Detroit, Michigan

Michael Erdil, MD
Industrial Medical Care Center
Hartford, Connecticut

Don C. Fisher, MD, MS
Presbyterian Occupational Health Network
Albuquerque, New Mexico

---

[1] Being listed in this section does not necessarily imply endorsement of the guideline products.

Garry A. Goldstein, MD
General Motors Corporation
Wilmington, Delaware

Robert J. Gorman, MD, MPH
Park Nicollet Medical Center
Minneapolis, Minnesota

Rowland G. Hazard, MD
University of Vermont
Burlington, Vermont

Timothy J. Key, MD, MPH
University of Alabama School of Medicine
Birmingham, Alabama

Ron R. Loeppke, MD, MPH
Corporate Health and Medical Programs, Inc.
Greeley, Colorado

Christel Mottur-Pilson, PhD
Internal Medicine Center to Advance Research & Education (IMCARE)
Washington, DC

Julie Graves Moy, MD, MPH
Baylor College of Medicine
Houston, Texas

Dennis A. Plante, MD
University of Vermont
Burlington, Vermont

Louis Sportelli, DC
Private Practice
Palmerton, Pennsylvania

Attachment A.

Algorithms

A1. Initial assessment of low back symptoms

A2. Treatment of acute low back problems on initial and followup visits

A3. Evaluation of the slow-to-recover patient (limitations > 4 weeks)

A4. Surgical considerations for patients with persistent sciatica

A5. Further care of acute low back problems.

Attachment B.

Pain Assessment Instruments

B1. Visual analog scale

B2. Pain drawing

Attachment C.

Patient Discussion Handouts

C1. Handout 1: Back problems?

C2. Handout 2: Seeking a reason for slow recover. . . .

C3. Handout 3: Overcoming your back problem

C4. Handout 4: When exercise is not helping

Explanation of Handouts

Four discussion handouts for patients are provided. They are sufficiently specific to address a full range of patient concerns. The patient's focus tends to change during treatment. Early concerns may focus on comfort, or fear of potentially dangerous causes of low back pain. Later, questions about special studies, procedures, and diagnoses may arise. The few patients having trouble overcoming their activity limitations may have to consider the relative benefits either of conditioning more vigorously or of changing their activity goals. These handouts are not intended to stand alone for all patients. Rather, they are designed to foster the clinician's discussions with patients about important issues, as needed.

- The first discussion handout is intended to prepare the patient for treatment recommendations. It can be provided to all patients if no serious condition is detected (probably at the first visit).

- The second discussion handout, which is only useful for the 10 percent of patients who are slowest to recover, helps patients understand about the use of special studies and the potential for diagnostic confusion.

- The third discussion handout is for the same 10 percent of patients when they are facing further treatment. It helps the patient understand the change in focus from merely treating symptoms and avoiding debilitation to building activity tolerance through safe exercises.

- The last discussion handout is only for those patients who, for whatever reasons, are experiencing difficulties in overcoming their activity limitations. It allows the clinician to help the patient develop an understanding of available options. If the patient is failing to overcome his

or her limitations and seeks no other alternatives, the clinician has an avenue to further address potential nonphysical (e.g., psychological and socioeconomic) pressures that can accompany activity limitations due to low back symptoms.

C1. Handout 1: Back problems?

The news is good. Your clinician has not found any dangerous causes for your back problem. Almost everyone has a low back problem at some time. In only one person out of 200 does the problem have a serious cause. A medical history and physical examination alone are very good at detecting these uncommon cases.

You should recover soon. Nine out of 10 persons with low back problems recover within 1 month, and most recover even sooner. Therefore, an x-ray of your back or other tests at this time would only waste your time. If your recovery happens to be slower than normal, your clinician will then look further for a reason.

Even with back symptoms, you may be able to continue your usual activities. But you might have to slow your pace. Strenuous activity or heavy lifting could give you trouble. If you work outside the home, much depends on the kind of work you do. Office work may require few changes. On the other hand, if your job involves heavy labor-like a furniture mover-you will probably have trouble working as usual right away.

Age also makes a difference. As we age, so do our spines. Activities that require speed and strength become harder to do. This happens to many people by age 30, to most people by age 40, and to nearly everyone by age 50. Consider your age as you plan your daily tasks when recovering from a back problem.

You can ease your discomfort safely. Your clinician will suggest safe ways for you to be more comfortable as you recover. But staying in bed is usually not the best thing. More than a few days in bed actually weakens your back and could cause your symptoms to last longer. Neither bed rest, medications, or any other remedies should be expected to do away with all the discomfort. It is important to be up and around as much as possible even if you are uncomfortable. The sooner you return to normal daily activities, the sooner your symptoms will disappear.

You may need to make changes in your daily activities. Sitting may not be comfortable. Sitting is not dangerous, but it puts more stress on the back than standing. While recovering, try to spend less time sitting. To make sitting easier, support the curve of your lower back with a towel or small pillow. If possible, use a chair or other seat with a slightly reclining back.

Lifting. Keep anything you must lift close to the belly button. Lifting a carton of milk or orange juice at arm's length can stress your back more than lifting 30 pounds held close to the body. Also try not to bend forward, twist, or reach when lifting.

Exercising can help your back. Your health care provider may suggest safe exercises such as walking, swimming, or riding a stationary bike. If done correctly, these exercises do not stress the back any more than does sitting on the side of your bed (which is not dangerous). What exercising does is keep your back muscles from becoming weakened by not enough activity. In addition, exercise is good for your general health, can speed your recovery, and may help protect you from future back problems. As your symptoms lessen, daily exercise will make it easier for you to resume your normal activities.

Points to remember:

- There is no hint of a serious problem.
- Your back symptoms are the kind that usually disappear within a month. Expect a rapid recovery.
- No medications or other treatments, including home remedies, can be expected to relieve all the discomfort immediately.
- You may need to change some daily activities to keep from irritating your back. But stay active enough to keep from weakening your muscles.
- If you are one of the few who is slow to recover, your clinician will look for the reason. Even if you are slow to recover, there is little chance of a serious reason for your back problem.

C2. Handout 2: Seeking a reason for slow recovery...

Special tests may be needed. If your back problem is slow to recover, your health care provider may consider special studies (tests) to find the reason. They may include blood tests; or an imaging study may be needed to view your spine. Nerve tests may help identify certain leg problems. The chances are good that your problem will not be serious. In only one person out of 200 do low back problems have a serious cause.

Why wait to do special studies? You may have read or heard of tests like MRI, CAT scan, or myelogram. These are special imaging studies. They use special equipment to provide different views of body structures like your spine. You may wonder why your health care provider did not order these tests in the first place. There is a good reason.

Imaging studies can be confusing. By themselves, they cannot tell the difference between possible causes of a back problem and common changes in the spine because of aging.

As we grow older, the spine changes. Almost half the population has aging changes in the spine as early as age 35. Yet most people who have such changes will not have a back problem lasting longer than 1 month. Remember that nine out of 10 people who have low back problems recover within 1 month. For these persons, imaging studies are unnecessary and confusion can be avoided. The tests could show a condition that is really not a problem and has no connection to back symptoms.

Imaging studies are seldom used alone. Surgery is never based on imaging studies alone. The studies could find something that is not really the cause of your problem. Before deciding whether imaging studies are needed, your health care provider should review your physical examination carefully. He or she may also do other kinds of tests to find evidence of a problem. Ask your health care provider to explain what tests are needed for you.

Table 1 lists a number of terms that are commonly used to describe (diagnose) the cause of low back symptoms. However, scientific studies have not been able to show a connection between these diagnoses and back symptoms. In addition, there is no evidence that these conditions benefit from surgery or other specialized forms of treatment.

Table 1. Common diagnoses used to explain back symptoms

Annular tear	Adult spondylolsis	Myofascitis
Fibromyalgia	Disc syndrome	Strain
Spondylosis	Lumbar disc disease	Facet syndrome
Degenerative joint disease	Sprain	Osteoarthritis of the spine
Disc derangement/disruption	Dislocation	Subluxation

When is surgery a choice? If your back symptoms affect your legs and are not getting better, a herniated lumbar disc (what many people call a slipped disc) may be the reason. The disc can press on a nerve root in your back and can either irritate the nerve or affect its function. If tests show strong evidence that this is happening, surgery to take the pressure off of the nerve may speed your recovery.

If your health care provider tells you that surgery is a possibility, ask about your choices. Ask what would happen without surgery. Before agreeing to surgery, get a second opinion from another health care provider. Also, ask about the tests that were done to suggest that surgery is the best approach for your back symptoms. Table 2 lists some conditions or diagnoses that sometimes benefit from surgery or other special treatment.

Table 2. Diagnoses that may benefit from surgery or other treatment.

Leg pain due to herniated lumber disc. Surgery is sometimes used to relieve the pressure on the nerve and can speed recovery if the diagnosis is based on strong evidence. Surgery should not be expected to make the back brand new.
Leg pain due to spinal stenosis. Spinal stenosis is an uncommon cause of walking limitation in the elderly. It is very rare under the age of 60. Surgery to take pressure off the nerves can improve walking distance and leg pain.
Leg pain with spondylolisthesis. Spondylolisthesis is measurable slippage of one vertebra upon another. In extremely rare cases, the slippage may be great enough to affect nerve root function. Surgery is sometimes used to take pressure off of the nerve and to fuse the vertebrae to prevent future slippage.
Fracture or dislocation. Surgery is commonly used to repair a fracture or dislocation if the fracture or dislocation affects the spinal nerves.
Spinal arthritis. If the condition is verified by a positive blood test and is not osteoarthritis or degenerative joint disease, nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, may be used.

Tests cannot always tell you the cause of your symptoms. Medical science cannot always explain the exact cause of most common low back symptoms. But medical science is very good at finding out if you have a dangerous condition causing your symptoms. If your problem is not caused by a serious condition, you can continue looking forward to recovery.

Exercise is important. Remember to continue to exercise as you were instructed by your health care provider and as described in Handout 1. It is important not to neglect your muscles. Exercise regularly!

Points to remember:

- Special studies are not needed for early detection and care of low back problems.

- Special studies can mislead if used alone. They can give additional information about a problem if used with other evidence.

- If your health care provider suggests surgery, ask what the evidence is for surgery. Ask about your choices and what would happen without surgery. Get a second opinion from another health care provider. Your surgeon will understand how important it is for you to be sure.

C3. Handout 3: Overcoming your back problem

By now your health care provider has given you the news that you can comfortably begin to get back to your daily activities. Even if you required surgery, you can now safely begin a specific, gentle exercise program to condition your body and your back muscles. This program will increase your back's ability to help you do the things you want and need to do.

Start with a simple, safe exercise such as walking, stationary bicycling, or swimming to build your general stamina. If you have been inactive, you may need to begin slowly and gradually increase your activity each day. Your health care provider will make specific recommendations

for safe exercises that do not stress your back any more than sitting on the side of your bed. Exercise helps because it:

- Trains the muscles that protect your back.
- Conditions your whole body.
- Stimulates the body to make its own powerful pain killers.
- Allows you to do more things more comfortably.

You also will find out what you can do easily and what takes more effort.

Reality about back problems. Although your recovery seems slow, your symptoms will continue to decrease unless you are inactive. However, your back may never feel as young as it once did. This happens to many of us by age 30, most by age 40, and just about everyone by age 50. Back problems often are the first sign of aging. You may have noticed that few professional athletes can continue competing beyond age 40. While some people may be able to resume strenuous activity after back problems as they get older, it usually needs to be at a slower pace. Most people need to shift gears and make changes in goals and activities as they grow older. Even at a slower pace, exercise will help you to be able to tolerate more of your daily activities.

Once you have had an activity-limiting back problem that lasts more than a few weeks, there is a 40 to 60 percent chance of having another back problem within the next few years. However, symptoms usually are not as severe in future episodes as in the first episode.

Success. As you begin to recover, the goal is to try to prevent back problems from returning or, if they do return,

being severe. Success will depend upon two factors. The first is the condition of your protective muscles. The second is the activities you ask your back to tolerate.

Ignoring either of these factors usually means more back problems. For example, a coal miner can expect further problems because mining is so demanding on the back. By contrast, a member of royalty who never needs to stress his or her back but does no conditioning exercises also can expect regular back problems. How well YOU do in the future will depend on what kind of condition you are in and what you ask your back to do. The more easily you and your protective muscles tire, the greater the chance that your symptoms will return. Taking action to condition the protective muscles of your back can reduce your future problems.

Safe exercises that are good for you and your back. Although exercises such as walking, stationary bicycling, or swimming are safe, you may feel some discomfort when you first start. After muscles become better conditioned, the soreness goes away. For example, during the winter when the weather is bad and many of us might stay indoors and be less active, the muscles of the back can lose their conditioning. When the first day of spring arrives and many of us go out to garden, the back may begin to ache when the out-of-condition protective muscles easily tire. Continuing such work daily over a few days or weeks reconditions the protective muscles so that they don't tire quite so easily, and the soreness disappears.

Remember that an increase in discomfort in an already painful back is common. But safe exercises (that involve less stress on the back than sitting on the side of the bed) should not harm your back. The shorter the time since beginning the conditioning, the greater the chance of increased soreness.

Conditioning requires regular activity. Regular activity is essential to obtain the conditioning effect to protect your back. Conditioning is achieved by building up to 30 minutes of continuous walking, stationary cycling, or swimming at a targeted heart rate (Table 1) or through jogging for 20 minutes. Conditioning works best if combined with your normal, daily activities both at home and at work. Stay as active as possible and exercise every day.

Your health care provider may have suggested ways to modify your daily chores to reduce the chance of irritating your back. Such changes at home or work are usually temporary. They are intended to give you time to improve the condition of your protective back muscles so that you can resume most normal activities. Table 2 offers guidelines to your health care provider on work recommendations to allow you reasonable time to recondition your back. Long-term activity tolerance varies greatly from person to person. Age and overall health are important factors, too. Regular, mild exercise may be enough for some. Others may be able to return to vigorous activities at a slower pace.

Points to remember:

- Both your level of physical conditioning and the stresses you put on your back will determine how often you will have problems and how severe they become.

- Conditioning usually requires daily work and commitment.

- Be sure your activity goal is realistic and you know what it will take to achieve it. Once you are over your back symptoms, or after a month of general conditioning training, your health care provider may suggest that you begin doing back muscle, trunk, or extremity exercises to gain further tolerance for specific tasks.

- If you have great difficulty resuming your previous daily routine, you may need to consider whether your old routine is realistic for you now.

Table 1. Building exercise tolerance

1. Try to maintain your daily activity as close to your normal level as possible.
2. As soon as possible begin walking, riding a stationary bicycle, or swimming. Choose what works for you.
3. Gradually build up to 30 minutes of activity without stopping.
4. Once you can tolerate 30 minutes of activity, establish a target heart rate that will help you to condition your muscles, heart, and respiratory system.
5. Then, your health care provider may also recommend some exercises for your back muscles.

Table 2. Guidelines for sitting and unassisted lifting

	Symptoms			
	Severe	**Moderate**	**Mild**	**None**
Sitting[1]	20 min	→	→	50 min
Unassisted Lifting[2]				
Men	20lbs	20lbs	60lbs	80lbs
Women	20lbs	20lbs	35lbs	40lbs

[1] Without getting up and moving around.

[2] Modification of NIOSH Lifting Guidelines, 1981, 1993. Gradually increase unassisted lifting limits to 60lbs (men) and 35 lbs (women) by 3 months even with continued symptoms. Limit twisting, bending, and reaching. Always lift close to belly button.

C4. Handout 4: When exercise is not helping

By now, your health care provider has made every effort to seek a medical reason for your continued activity limitation. You are well into the exercise program intended to condition your back for the activities you need to do. Unfortunately, for some people success is less easy and slower to achieve. If this is the case, there are many things to consider.

Age is important. Few middle-aged persons have a back that is as strong as it was at age 18. Medical science presently cannot reverse the aging process that limits activities requiring both speed and strength. Young people may find it hard to accept these limitations. Older people commonly find it difficult to give up or alter activities they have been doing for a long time.

Some people continue to look for a cure when progress is slow. Such efforts rarely succeed. Consider a basketball star like Larry Bird. Money was surely no object in seeking a cure for his back problem. He could afford the most expensive medical care and conditioning programs. Nevertheless, he was forced to retire at age 34. His back could no longer tolerate the physical stress of basketball.

How many athletes in strenuous sports can compete beyond age 35 or 40? Very few! Most of us must adjust our activities as we age, regardless of occupation or level of physical conditioning, many by age 30, most by age 40, and just about all of us by age 50. Some people can continue strenuous activities into their older years, especially if they are able to do it at their own pace. Others may need to consider change.

Be realistic. Ask yourself three key questions about your daily activity requirements:

- Can a reasonable exercise program overcome my back problem?

- Will it be possible to continue a more time-consuming exercise program and my usual daily requirements long term?

- Is there any way I can change my activity requirements now or in the future?

If a reasonable exercise program is not helping you, there are several options: (1) You can choose to put up with discomfort and expect some setbacks. (2) You can begin a more time-consuming conditioning program. (3) You can change the pace of doing difficult activities. This may include a job change. People may use a combination of the three approaches.

Considering a job change is difficult, especially if back problems continue to limit your ability to do your work. Again, ask yourself this important question: "Is my activity goal realistic, or do I need to look at my options?" A review now might help you avoid a similar dilemma in the near or distant future, when increased age may work against you. Being a few years older sometimes makes a big difference in the chance of changing jobs. Some creative planning could benefit you now, or in the future, especially if your job activities present a problem.

When considering a job or career change, it is important to gather information from many sources. Some possibilities include private career counselors, local or State employment offices, and veterans' or consumer groups. You may also want to talk to someone working in the field.

Information is your ally. Whether or not you explore job opportunities alone or with professional help, remember this important point:

> Only you can find a way to adjust your life, your job, or your plans in a way that is right for you.

Complementary Care: When Is It Appropriate? Who Will Provide It?

The Agency for Health Care Policy and Research (AHCPR) recently made history when it concluded that spinal manipulative therapy is the most effective and cost-effective treatment for acute low back pain [1]. The 1994 guidelines for acute low back pain developed by AHCPR concluded that spinal manipulation hastens recovery from acute low back pain and recommended that this therapy be used in combination with or as an alternative to nonsteroidial anti-inflammatory drugs [1]. At the same time, AHCPR concluded that various traditional methods, such as bed rest, traction, and other physical and pharmaceutical therapies were less effective than spinal manipulation and cautioned against lumbar surgery except in the most severe cases. Perhaps most significantly, the guidelines state that unlike nonsurgical interventions, spinal manipulation offers both pain relief and functional improvement. One might conclude that for acute low back pain not caused by fracture, tumor, infection, or the cauda equina syndrome, spinal manipulation is the treatment of choice.

Because acute low back pain is the most prevalent ailment and most frequent cause of disability for persons younger than 45 years of age in the United States [1], adherence to these practice guidelines could substantially increase the numbers of patients referred for spinal manipulation. Chiropractors provide 94% of spinal manipulation [2,3]; limited numbers of physical therapists and traditional osteopathic physicians provide the remainder.

In a 1994 RAND publication, Shekelle and colleagues reported on studies of the use and costs of chiropractic care [4]. These authors have followed this work by reporting, in this issue, adherence by chiropractors to expert

recommendations for the use of manipulation for the treatment of low back pain [5].

It is important to note that Shekelle and colleagues focus on the decision to initiate treatment; they do not address the appropriateness of the frequency or duration of treatment. They also provide no data on actual clinical outcomes but rather simply examine the application of therapy according to standard criteria. "Appropriate" as defined in their study does not necessarily mean "beneficial."

In this study, the proportions of chiropractic spinal manipulation judged to be appropriate and inappropriate were similar to proportions previously described for certain allopathic medical procedures. However, more than one fourth of patients received spinal manipulation for indications that were judged inappropriate for this type of therapy. Therefore, effort must be placed on reducing the amount of inappropriate chiropractic spinal manipulation, as is being done for such medical procedures as carotid endarterectomy [6], coronary artery bypass surgery [7], hysterectomy [8], and tympanostomy [9].

Shekelle and colleagues' study may be an indicator of what is to come. The AHCPR is developing new guidelines for the use of chiropractic manipulation in chronic headache. The Fo ndation for Chiropractic Education and Research is supporting other studies by chiropractors, and a Consortial Center for Chiropractic Research has been established at the Palmer Center for Chiropractic Research in Davenport, Iowa, with support from the National Institutes of Health. There remains much controversy within the chiropractic profession about the appropriate use of various therapies, such as high-velocity adjustment. Moreover, no therapy works equally well for everyone, even when appropriately used. We need more

research to identify patients and conditions that are likely to benefit from alternative therapies.

Issues relating to "appropriate" complementary care extend far beyond the scope of Shekelle and colleagues' study. When should care be initiated? What is the general quality of the care provided? How effective is that care? Who will provide this high-quality, effective care? Answering all of these questions is crucial, but the last one is of particular concern. Without enough well-trained alternative care practitioners, the potential for inappropriate care will be great.

Born in the U.S. Midwest 100 years ago, chiropractic is a uniquely American contribution to health care. It drew from "vitalist" concepts and "energetic" healing traditions that were then current in the practice of an eclectic U.S. medicine and from the desire for drugless healing in reaction to the toxicity of the materia medica of that era. Despite this rather long history, social, political and economic pressures have limited the chiropractic workforce to 56 000 practitioners in the world (52 000 of them in the United States), plus a much smaller number of "traditional" osteopathic physicians and others who practice spinal manipulation [10]. In comparison, the mainstream medical workforce in the United States consists of about 600 000 physicians.

Even with these limitations on its growth, chiropractic is clearly the largest complementary health care force in the United States. Chiropractic is also the most "professionalized" of the complementary healing traditions available in the United States, with licensure in all 50 states, educational accreditation standards, continuing education requirements, and active research and investigation. Less organized and less professionalized disciplines of complementary care may be poorly prepared to develop

guidelines and conduct research. In addition, the emphasis on tailoring complementary therapy to the individual patient may be at odds with the biomedical concepts of treatment protocols, practice guidelines, and population-based research [11].

Acupuncture, which also may be an effective therapy for back pain, is a discipline that is beginning to wrestle with these issues on a wide scale. The November 1997 National Institutes of Health Consensus Development Conference on Acupuncture concluded that acupuncture is safe, is efficacious for some clinical conditions, appears promising for others, and requires additional clinical research. However, only approximately 3000 physician-acupuncturists are practicing in the United States. Acupuncture is licensed in just two thirds of U.S. states and Washington, D.C. [12]. Because acupuncture has long been relegated to an underground, marginalized status in the United States, it is not well organized or professionalized compared with mainstream medicine or even chiropractic. As physicians are becoming increasingly willing and able to justify referral for complementary care, how will acupuncture and other healing traditions, now hundreds or thousands of years old, become more "professional" to meet the demand for care and the opportunities for integration into mainstream medicine?

We must foster the development of training, research, and clinical protocols to support integration of complementary medicine in a way that promotes favorable clinical outcomes. Alternative medicine can benefit from the kind of support from which mainstream medicine has benefited over the years. When all is said and done, what works will no longer be called mainstream or complementary-it will just be called good medicine.

Marc S. Micozzi, MD, PhD
College of Physicians of Philadelphia
Philadelphia, PA 19103

Requests for Reprints: Marc S. Micozzi, MD, PhD, College of Physicians, 19 South 22nd Street, Philadelphia, PA 19103.

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Supreme Court, U.S.
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In The
Supreme Court of the United States

AMERICAN CHIROPRACTIC ASSOCIATION, INCORPORATED, a non-profit corporation, *et al.*,
Petitioners,

v.

TRIGON HEALTHCARE, INCORPORATED, *et al.*,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

APPENDIX B TO PETITION FOR WRIT OF CERTIORARI

George P. McAndrews
Counsel of Record
Steven J. Hampton
Patrick J. Arnold, Jr.
Sharon Hwang
James P. Murphy
Peter J. McAndrews
Ronald A. Dicerbo
MCANDREWS, HELD & MALLOY, LTD.
34th Floor
500 West Madison Street
Chicago, IL 60661
(312) 775-8000

Thomas R. Daly
ODIN, FELDMAN, & PITTLEMAN, P.C.
9032 Lee Highway
Suite 1100
Fairfax, VA 22031
(703) 218-2100

William G. Shields
THORSEN & SCHER
3810 Augusta Ave.
Richmond, VA 23230
(804) 359-3000

Counsel for Petitioners

THE LEX GROUP • 1108 East Main Street • Suite 1400 • Richmond, Virginia 23219
(804) 644-4419 • (800) 856-4419 • Fax: (804) 644-3660 • www.thelexgroup.com

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Clinical Practice Guideline

Quick Reference Guide for Clinicians

Number 14

HE 20.6530/2:14

Acute Low Back Problems in Adults: Assessment and Treatment

COMPLETED

U.S. Department of Health and Human Services
Public Health Service
Agency for Health Care Policy and Research

Acute Low Back Problems in Adults

TR03140242

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The Clinical Practice Guideline on which this Quick Reference Guide for Clinicians is based was developed by a multidisciplinary, private-sector panel comprising health care professionals and a consumer representative sponsored by the Agency for Health Care Policy and Research (AHCPR). Panel members were:

Stanley J. Bigos, MD (Chair)
Reverend O. Richard Bowyer
G. Richard Braen, MD
Kathleen C. Brown, PhD, RN
Richard A. Deyo, MD, MPH
Scott Haldeman, MD, PhD, DC
John L. Hart, DO
Ernest W. Johnson, MD
Robert B. Keller, MD
Daniel K. Kido, MD
Matthew H. Liang, MD, MPH
Roger M. Nelson, PhD, PTT
Margareta Nordin, Dr. Med. Sc.
Bernice D. Owen, PhD, RN
Malcolm H. Pope, Dr. Med. Sc., PhD
Richard K. Schwartz, MS, OTR
Donald H. Stewart, Jr., MD
Jeffrey L. Susman, MD
John J. Triano, DC, MA
Lucius Tripp, MD, MPH
Dennis Turk, PhD
Clark Watts, MD, JD
James Weinstein, DO

Special consultants to the panel were: Michele Battié, PT, PhD; Claire Bombardier, MD; Nortin Hadler, MD; Alf Nachemson, MD, PhD; Gordon Waddell, MD. John Holland, MD, MPH and John Webster, MD served as project directors. Project methodologists were David Schriger, MD, MPH and Paul Shekelle, MD,MPH.

An explicit, science-based methodology was employed along with expert clinical judgment to develop specific statements on patient assessment and management on acute low back problems. Extensive literature searches were conducted and critical reviews and syntheses were used to evaluate empirical evidence and significant outcomes. Peer review and pilot testing were undertaken to evaluate the validity, reliability, and utility of the guideline in clinical practice.

This *Quick Reference Guide for Clinicians* presents a clinical strategy for applying the statements and recommendations from the *Clinical Practice Guideline*. The latter provides a description of the guideline development process, thorough analysis and discussion of the available research, critical evaluation of the assumptions and knowledge of the field, more complete information for health care decisionmaking, consideration for patients with special needs, and references. Decisions to adopt particular recommendations from either publication must be made by practitioners in light of available resources and circumstances presented by the individual patient.

AHCPR invites comments and suggestions from users for consideration in development and updating of future guidelines.

Please send written comments to:

Director, Office of the Forum for Quality and
Effectiveness in Health Care
AHCPR, Willco Building, Suite 310
6000 Executive Boulevard
Rockville, MD 20852

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Quick Reference Guide for Clinicians

Number 14

Acute Low Back Problems in Adults: Assessment and Treatment

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U.S. Department of Health and Human Services
Public Health Service
Agency for Health Care Policy and Research
Rockville, Maryland

AHCPR Publication No. 95-0643
December 1994

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Abstract

This *Quick Reference Guide for Clinicians* contains highlights from the *Clinical Practice Guideline* version of *Acute Low Back Problems in Adults*, which was developed by a private-sector panel of health care providers and consumers. The *Quick Reference Guide* is an example of how a clinician might implement the panel's findings and recommendations on the management of acute low back problems in working-age adults. Topics covered include the initial assessment of patients presenting with acute low back problems, identification of red flags that may indicate the presence of a serious underlying medical condition, initial management, special studies and diagnostic considerations, and further management considerations. Instructions for clinical testing for sciatic tension, recommendations for sitting and unassisted lifting, tests for identification of clinical pathology, and algorithms for patient management are included.

Suggested citation

This document is in the public domain and may be used and reprinted without special permission. AHCPR appreciates citation as to source and the suggested format is provided below:

Bigos S, Bowyer O, Braen G, et al. *Acute Low Back Problems in Adults.* Clinical Practice Guideline, Quick Reference Guide Number 14. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research. AHCPR Pub. No. 95-0643. December 1994.

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Purpose and Scope

Low back problems affect virtually everyone at some time during their life. Surveys indicate a yearly prevalence of symptoms in 50 percent of working age adults; 15-20 percent seek medical care. Low back problems rank high among the reasons for physician office visits and are costly in terms of medical treatment, lost productivity, and nonmonetary costs such as diminished ability to perform or enjoy usual activities. In fact, for persons under age 45, low back problems are the most common cause of disability.

Acute low back problems are defined as activity intolerance due to lower back or back-related leg symptoms of less than 3 months' duration. About 90 percent of patients with acute low back problems spontaneously recover activity tolerance within 1 month. The approach to a new episode in a patient with a recurrent low back problem is similar to that of a new acute episode.

The findings and recommendations included in the *Clinical Practice Guideline* define a paradigm shift away from focusing care exclusively on the pain and toward helping patients improve activity tolerance. The intent of this *Quick Reference Guide* is to bring to life this paradigm shift. The guide provides information on the detection of serious conditions that occasionally cause low back symptoms (conditions such as spinal fracture, tumor, infection, cauda equina syndrome, or non-spinal conditions). However, treatment of these conditions is beyond the scope of this guideline. In addition, the guideline does not address the care of patients younger than 18 years or those with chronic back problems (back-related activity limitations of greater than 3 months' duration).

Initial Assessment

- Seek potentially dangerous underlying conditions.
- In the absence of signs of dangerous conditions, there is no need for special studies since 90 percent of patients will recover spontaneously within 4 weeks.

A focused medical history and physical examination are sufficient to assess the patient with an acute or recurrent limitation due to low back symptoms of less than 4 weeks duration. Patient responses and findings on the history and physical examination, referred to as "red flags" (Table 1), raise suspicion of serious underlying spinal conditions. Their absence rules out the need for special studies during the first 4 weeks of symptoms when spontaneous recovery is expected. The medical history and physical examination can also alert the clinician to non-spinal pathology (abdominal, pelvic, thoracic) that

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can present as low back symptoms. Acute low back symptoms can then be classified into one of three working categories:

- *Potentially serious spinal condition*—tumor, infection, spinal fracture, or a major neurologic compromise, such as cauda equina syndrome, suggested by a red flag.
- *Sciatica*—back-related lower limb symptoms suggesting lumbosacral nerve root compromise.
- *Nonspecific back symptoms*—occurring primarily in the back and suggesting neither nerve root compromise nor a serious underlying condition.

Table 1. Red flags for potentially serious conditions

Possible fracture	Possible tumor or infection	Possible cauda equina syndrome
From medical history		
Major trauma, such as vehicle accident or fall from height. Minor trauma or even strenuous lifting (in older or potentially osteoporotic patient).	Age over 50 or under 20. History of cancer. Constitutional symptoms, such as recent fever or chills or unexplained weight loss. Risk factors for spinal infection: recent bacterial infection (e.g., urinary tract infection); IV drug abuse; or immune suppression (from steroids, transplant, or HIV). Pain that worsens when supine; severe nighttime pain.	Saddle anesthesia. Recent onset of bladder dysfunction, such as urinary retention, increased frequency, or overflow incontinence. Severe or progressive neurologic deficit in the lower extremity.
From physical examination		
		Unexpected laxity of the anal sphincter. Perianal/perineal sensory loss. Major motor weakness: quadriceps (knee extension weakness); ankle plantar flexors, evertors, and dorsiflexors (foot drop).

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Medical History

In addition to detecting serious conditions and categorizing back symptoms, the medical history establishes rapport between the clinician and patient. The patient's description of present symptoms and limitations, duration of symptoms, and history of previous episodes defines the problem. It also provides insight into concerns, expectations, and nonphysical (psychological and socioeconomic) issues that may alter the patient's response to treatment. Assessment tools such as pain drawings and visual analog pain-rating scales may help further document the patient's perceptions and progress.

A patient's estimate of personal activity intolerance due to low back symptoms contributes to the clinical assessment of the severity of the back problem, guides treatment, and establishes a baseline for recommending daily activities and evaluating progress.

Open-ended questions, such as those listed below, can gauge the need for further discussion or specific inquiries for more detailed information:

- *What are your symptoms?*
  - Pain, numbness, weakness, stiffness?
  - Located primarily in back, leg, or both?
  - Constant or intermittent?
- *How do these symptoms limit you?*
  - How long can you sit, stand, walk?
  - How much weight can you lift?
- *When did the current limitations begin?*
  - How long have your activities been limited? More than 4 weeks?
  - Have you had similar episodes previously?
  - Previous testing or treatment?
- *What do you hope we can accomplish during this visit?*

Physical Examination

Guided by the medical history, the physical examination includes:

- General observation of the patient.
- A regional back exam.
- Neurologic screening.
- Testing for sciatic nerve root tension.

The examination is mostly subjective since patient response or interpretation is required for all parts except reflex testing and circumferential measurements for atrophy.

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Addressing Red Flags

Physical examination evidence of severe neurologic compromise that correlates with the medical history may indicate a need for immediate consultation. The examination may further modify suspicions of tumor, infection or significant trauma. A medical history suggestive of non-spinal pathology mimicking a back problem may warrant examination of pulses, abdomen, pelvis, or other areas.

Observation and Regional Back Examination

Limping or coordination problems indicate the need for specific neurologic testing. Severe guarding of lumbar motion in all planes may support a suspected diagnosis of spinal infection, tumor, or fracture. However, given marked variations among persons with and without symptoms, range-of-motion measurements of the back are of limited value.

Vertebral point tenderness to palpation, when associated with other signs or symptoms, may be suggestive of but not specific for spinal fracture or infection. Palpable soft-tissue tenderness is, by itself, an even less specific or reliable finding.

Neurologic Screening

The neurologic examination can focus on a few tests that seek evidence of nerve root impairment, peripheral neuropathy, or spinal cord dysfunction. Over 90 percent of all clinically significant lower extremity radiculopathy due to disc herniation involves the L5 or S1 nerve root at the L4-5 or L5-S1 disc level. The clinical features of nerve root compression are summarized in Figure 1.

- *Testing for Muscle Strength.* The patient's inability to toe walk (calf muscles, mostly S1 nerve root), heel walk (ankle and toe dorsiflexor muscles, L5 and some L4 nerve roots), or do a single squat and rise (quadriceps muscles, mostly L4 nerve root) may indicate muscle weakness. Specific testing of the dorsiflexor muscles of the ankle or great toe (suggestive of L5 or some L4 nerve root dysfunction), hamstrings and ankle evertors (L5-S1), and toe flexors (S1) is also important.
- *Circumferential Measurements.* Muscle atrophy can be detected by circumferential measurements of the calf and thigh bilaterally. Differences of less than 2 cm in measurements of the two limbs at the same level may be a normal variation. Symmetrical muscle bulk and strength are expected unless the patient has a neurologic impairment or a history of lower extremity muscle or joint problem.
- *Reflexes.* The ankle jerk reflex tests mostly the S1 nerve root and the knee jerk reflex tests mostly the L4 nerve root; neither tests the L5 nerve root. The reliability of reflex testing can be diminished in the presence of adjacent joint or muscle problems. Up-going toes in response to stroking the plantar footpad (Babinski or plantar

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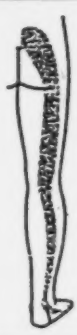
response) may indicate upper motor-neuron abnormalities (such as myelopathy or demyelinating disease) rather than a common low back problem.

- *Sensory Examination.* Testing light touch or pressure in the medial (L4), dorsal (L5), and lateral (S1) aspects of the foot (Figure 1) is usually sufficient for sensory screening.

Figure 1. Testing for lumbar nerve root compromise.

Nerve root	L4	L5	S1
Pain			
Numbness			
Motor weakness	Extension of quadriceps.	Dorsilflexion of great toe and foot.	Plantar flexion of great toe and foot.
Screening exam	Squat & rise.	Heel walking.	Walking on toes.
Reflexes	Knee jerk diminished.	None reliable.	Ankle jerk diminished.

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Clinical tests for sciatic tension

The straight leg raising (SLR) test (Figure 2) can detect tension on the L5 and/or S1 nerve root. SLR may reproduce leg pain by stretching nerve roots irritated by a disc herniation.

Figure 2. Instructions for the Straight Leg Raising (SLR) Test

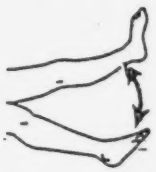
(1) Ask the patient to lie as straight as possible on a table in the supine position.

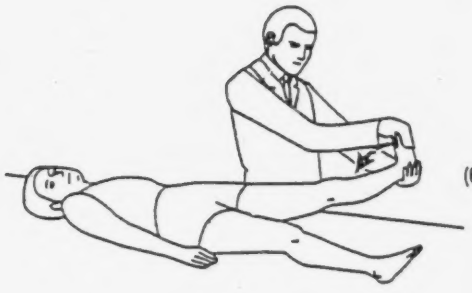
(2) With one hand placed above the knee of the leg being examined, exert enough firm pressure to keep the knee fully extended. Ask the patient to relax.

(3) With the other hand cupped under the heel, slowly raise the straight limb. Tell the patient, "If this bothers you, let me know, and I will stop."

4) Monitor for any movement of the pelvis before complaints are elicited. True sciatic tension should elicit complaints before the hamstrings are stretched enough to move the pelvis.

(5) Estimate the degree of leg elevation that elicits complaint from the patient. Then determine the most distal area of discomfort: back, hip, thigh, knee, or below the knee.





(6) While holding the leg at the limit of straight leg raising, dorsiflex the ankle. Note whether this aggravates the pain. Internal rotation of the limb can also increase the tension on the sciatic nerve roots.

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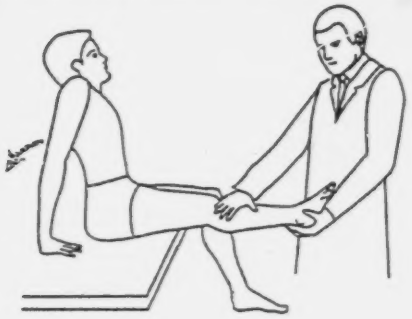
Pain below the knee at less than 70 degrees of straight leg raising, aggravated by dorsiflexion of the ankle and relieved by ankle plantar flexion or external limb rotation, is most suggestive of tension on the L5 or S1 nerve root related to disc herniation. Reproducing back pain alone with SLR testing does not indicate significant nerve root tension.

Crossover pain occurs when straight raising of the patient's well limb elicits pain in the leg with sciatica. Crossover pain is a stronger indication of nerve root compression than pain elicited from raising the straight painful limb.

Sitting knee extension (Figure 3) can also test sciatic tension. The patient with significant nerve root irritation tends to complain or lean backward to reduce tension on the nerve.

Figure 3. Instructions for sitting knee extension test.



With the patient sitting on a table, both hip and knees flexed at 90 degrees, slowly extend the knee as if evaluating the patella or bottom of the foot. This maneuver stretches nerve roots as much as a moderate degree of supine SLR.

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Inconsistent Findings and Pain Behavior

The patient who embellishes a medical history, exaggerates pain drawings, or provides responses on physical examination inconsistent with known physiology can be particularly challenging. A strongly positive supine straight leg raising test without complaint on sitting knee extension and inconsistent responses on examination raise a suspicion that nonphysical factors may be affecting the patient's responses. "Pain behaviors" (verbal or nonverbal communication of distress or suffering) such as amplified grimacing, distorted gait or posture, moaning, and rubbing of painful body parts may also cloud medical issues and even evoke angry responses from the clinician.

Interpreting inconsistencies or pain behaviors as malingering does not benefit the patient or the clinician. It is more useful to view such behavior and inconsistencies as the patient's attempt to enlist the practitioner as an advocate, a plea for help. The patient could be trapped in a job where activity requirements are unrealistic relative to the person's age or health. In some cases, the patient may be negotiating with an insurer or be involved in legal actions. In patients with recurrent back problems, inconsistencies and amplifications may simply be habits learned during previous medical evaluations. In working with these patients, the clinician should attempt to identify any psychological or socioeconomic pressures that might be influenced in a positive manner. The overall goal should always be to facilitate the patient's recovery and avoid the development of chronic low back disability.

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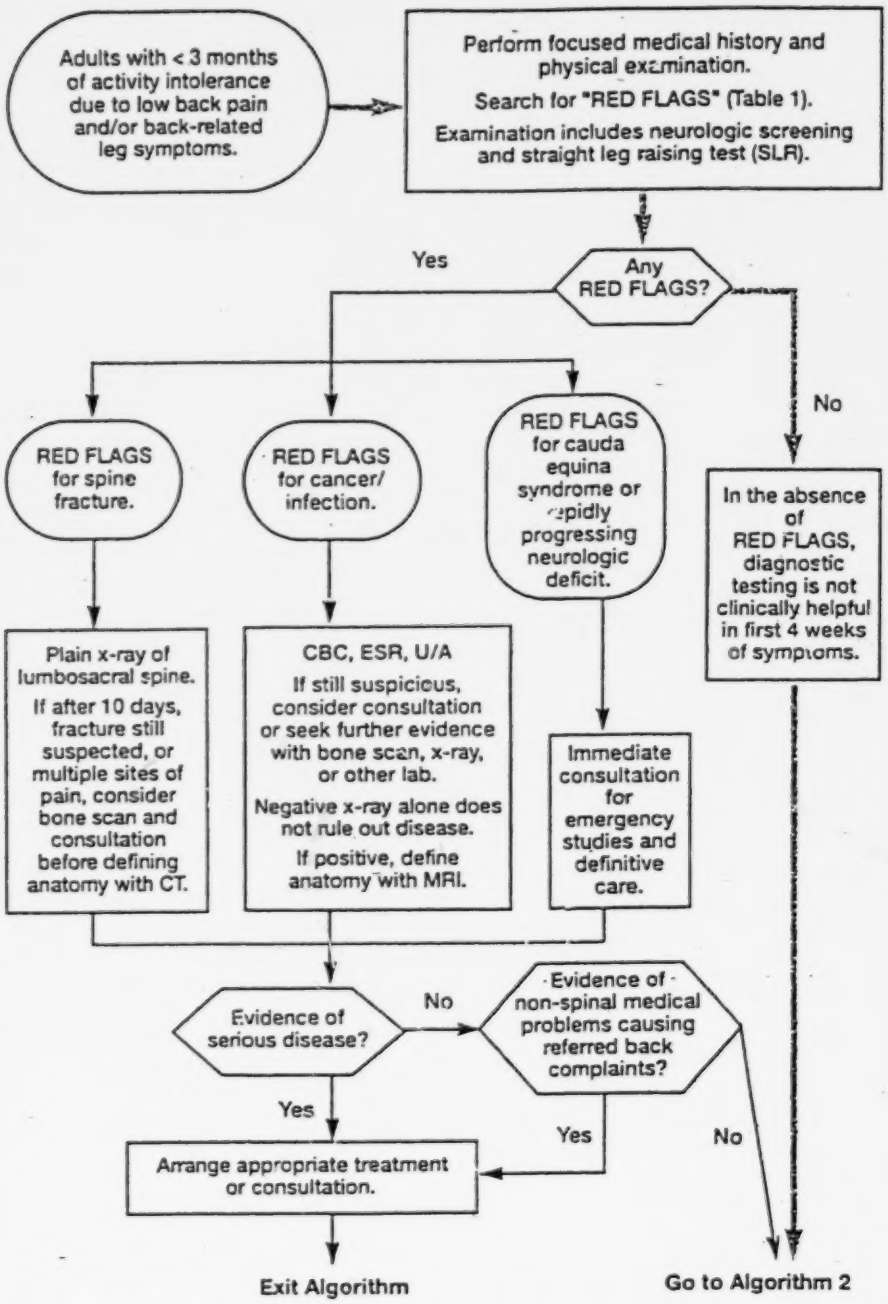
Algorithm 1:
Initial evaluation of acute low back problem



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- Education and assurance.
- Patient comfort.
- Activity alterations.

Patient Education

If the initial assessment detects no serious condition, assure the patient that there is "no hint of a dangerous problem" and that "a rapid recovery can be expected." The need for education will vary among patients and during various stages of care. An obviously apprehensive patient may require a more detailed explanation. Patients with sciatica may have a longer expected recovery time than patients with nonspecific back symptoms and thus may need more education and reassurance. Any patient who does not recover within a few weeks may need more extensive education about back problems and the reassurance that special studies may be considered if recovery is slow.

Patient Comfort

Comfort is often a patient's first concern. Nonprescription analgesics will provide sufficient pain relief for most patients with acute low back symptoms. If treatment response is inadequate, as evidenced by continued symptoms and activity limitations, prescribed pharmaceuticals or physical methods may be added. Comorbid conditions, side effects, cost, and provider/patient preference should guide the clinician's choice of recommendations. Table 2 summarizes comfort options.

Oral Pharmaceuticals

The safest effective medication for acute low back problems appears to be acetaminophen. Nonsteroidal anti-inflammatory drugs (NSAIDs), including aspirin and ibuprofen, are also effective although they can cause gastrointestinal irritation/ulceration or (less commonly) renal or allergic problems. Phenylbutazone is not recommended due to risks of bone marrow suppression. Acetaminophen may be used safely in combination with NSAIDs or other pharmacologic or physical therapeutics, especially in otherwise healthy patients.

Muscle relaxants seem no more effective than NSAIDs for treating patients with low back symptoms, and using them in combination with NSAIDs has no demonstrated benefit. Side effects including drowsiness have been reported in up to 30 percent of patients taking muscle relaxants.

Opioids appear no more effective than safer analgesics for managing low back symptoms. Opioids should be avoided if possible and, when chosen, used only for a short time. Poor patient tolerance and risks of drowsiness, decreased reaction time, clouded judgment, and potential misuse/dependence have been reported in up to 35 percent of patients. Patients should be warned of these potentially debilitating problems.

Table 2: Symptom control methods

Recommended		
Nonprescription analgesics		
Acetaminophen (safest) NSAIDs (Aspirin,[1] Ibuprofen[1])		
Prescribed pharmaceutical methods	**Prescribed physical methods**	
Nonspecific low back symptoms and/or sciatica	**Nonspecific low back symptoms**	**Sciatica**
Other NSAIDs[1]	Manipulation (in place of medication or a shorter trial if combined with NSAIDs)	
Options		
Nonspecific low back symptoms and/or sciatica	**Nonspecific low back symptoms**	**Sciatica**
Muscle relaxants[2,3,4] Opioids[2,3,4]	Physical agents and modalities[2] (heat or cold modalities for home programs only) Shoe insoles[2]	Manipulation (in place of medication or a shorter trial if combined with NSAIDs) Physical agents and modalities[2] (heat or cold modalities for home programs only) Few days' rest[4] Shoe insoles[2]

[1]Aspirin and other NSAIDs are not recommended for use in combination with one another due to the risk of GI complications.
[2]Equivocal efficacy.
[3]Significant potential for producing drowsiness and debilitation; potential for dependency.
[4]Short course (few days only) for severe symptoms.

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Physical Methods

- ***Manipulation,*** defined as manual loading of the spine using short or long leverage methods, is safe and effective for patients in the first month of acute low back symptoms without radiculopathy. For patients with symptoms lasting longer than 1 month, manipulation is probably safe but its efficacy is unproven. If manipulation has not resulted in symptomatic and functional improvement after 4 weeks, it should be stopped and the patient reevaluated.
- ***Traction*** applied to the spine has not been found effective for treating acute low back symptoms.
- ***Physical modalities*** such as *massage, diathermy, ultrasound, cutaneous laser treatment, biofeedback,* and *transcutaneous electrical nerve stimulation (TENS)* also have no proven efficacy in the treatment of acute low back symptoms. If requested, the clinician may wish to provide the patient with instructions on self-application of heat or cold therapy for temporary symptom relief.
- ***Invasive techniques*** such as *needle acupuncture* and *injection procedures* (injection of trigger points in the back; injection of facet joints; injection of steroids, lidocaine, or opioids in the epidural space) have no proven benefit in the treatment of acute low back symptoms.
- ***Other miscellaneous therapies*** have been evaluated. No evidence indicates that *shoe lifts* are effective in treating acute low back symptoms or limitations, especially when the difference in lower limb length is less than 2 cm. Shoe insoles are a safe and inexpensive option if requested by patients with low back symptoms who must stand for prolonged periods. Low back corsets and back belts, however, do not appear beneficial for treating acute low back symptoms.

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Activity Alteration

To avoid both undue back irritation and debilitation from inactivity, recommendations for alternate activity can be helpful. Most patients will not require bed rest. Prolonged bed rest (more than 4 days) has potential debilitating effects, and its efficacy in the treatment of acute low back problems is unproven. Two to four days of bed rest are reserved for patients with the most severe limitations (due primarily to leg pain).

Avoiding undue back irritation. Activities and postures that increase stress on the back also tend to aggravate back symptoms. Patients limited by back symptoms can minimize the stress of lifting by keeping any lifted object close to the body at the level of the navel. Twisting, bending, and reaching while lifting also increase stress on the back. Sitting, although safe, may aggravate symptoms for some patients. Advise these patients to avoid prolonged sitting and to change position often. A soft support placed at the small of the back, armrests to support some body weight, and a slight recline of the chair back may make required sitting more comfortable.

Avoiding debilitation. Until the patient returns to normal activity, aerobic (endurance) conditioning exercise such as walking, stationary biking, swimming, and even light jogging may be recommended to help avoid debilitation from inactivity. An incremental, gradually increasing regimen of aerobic exercise (up to 20 to 30 minutes daily) can usually be started within the first 2 weeks of symptoms. Such conditioning activities have been found to stress the back no more than sitting for an equal time period on the side of the bed. Patients should be informed that exercise may increase symptoms slightly at first. If intolerable, some exercise alteration is usually helpful.

Conditioning exercises for trunk muscles are more mechanically stressful to the back than aerobic exercise. Such exercises are not recommended during the first few weeks of symptoms, although they may later help patients regain and maintain activity tolerance.

There is no evidence to indicate that back-specific exercise machines are effective for treating acute low back problems. Neither is there evidence that stretching of the back helps patients with acute symptoms.

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Work Activities

When requested, clinicians may choose to offer specific instructions about activity at work for patients with acute limitations due to low back symptoms. The patient's age, general health, and perceptions of safe limits of sitting, standing, walking or lifting (noted on initial history) can help provide reasonable starting points for activity recommendations. Table 3 provides a guide for recommendations about sitting and lifting. The clinician should make clear to patients and employers that:

- Even moderately heavy unassisted lifting may aggravate back symptoms.
- Any restrictions are intended to allow for spontaneous recovery or time to build activity tolerance through exercise.

Activity restrictions are prescribed for a short time period only, depending upon work requirements (no benefits apparent beyond 3 months).

Table 3. Guidelines for sitting and unassisted lifting

	Symptoms						
	Severe	→	Moderate	→	Mild	→	None
Sitting[1]	20 min	→	→	→	→	→	50 min
Unassisted lifting[2]							
Men	20 lbs	→	20 lbs	→	60 lbs	→	80 lbs
Women	20 lbs	→	20 lbs	→	35 lbs	→	40 lbs

[1]Without getting up and moving around.
[2]Modification of NIOSH Lifting Guidelines, 1981, 1993. Gradually increase unassisted lifting limits to 60 lbs (men) and 35 lbs (women) by 3 months even with continued symptoms. Instruct patient to limit twisting, bending, reaching while lifting and to hold lifted object as close to navel as possible.

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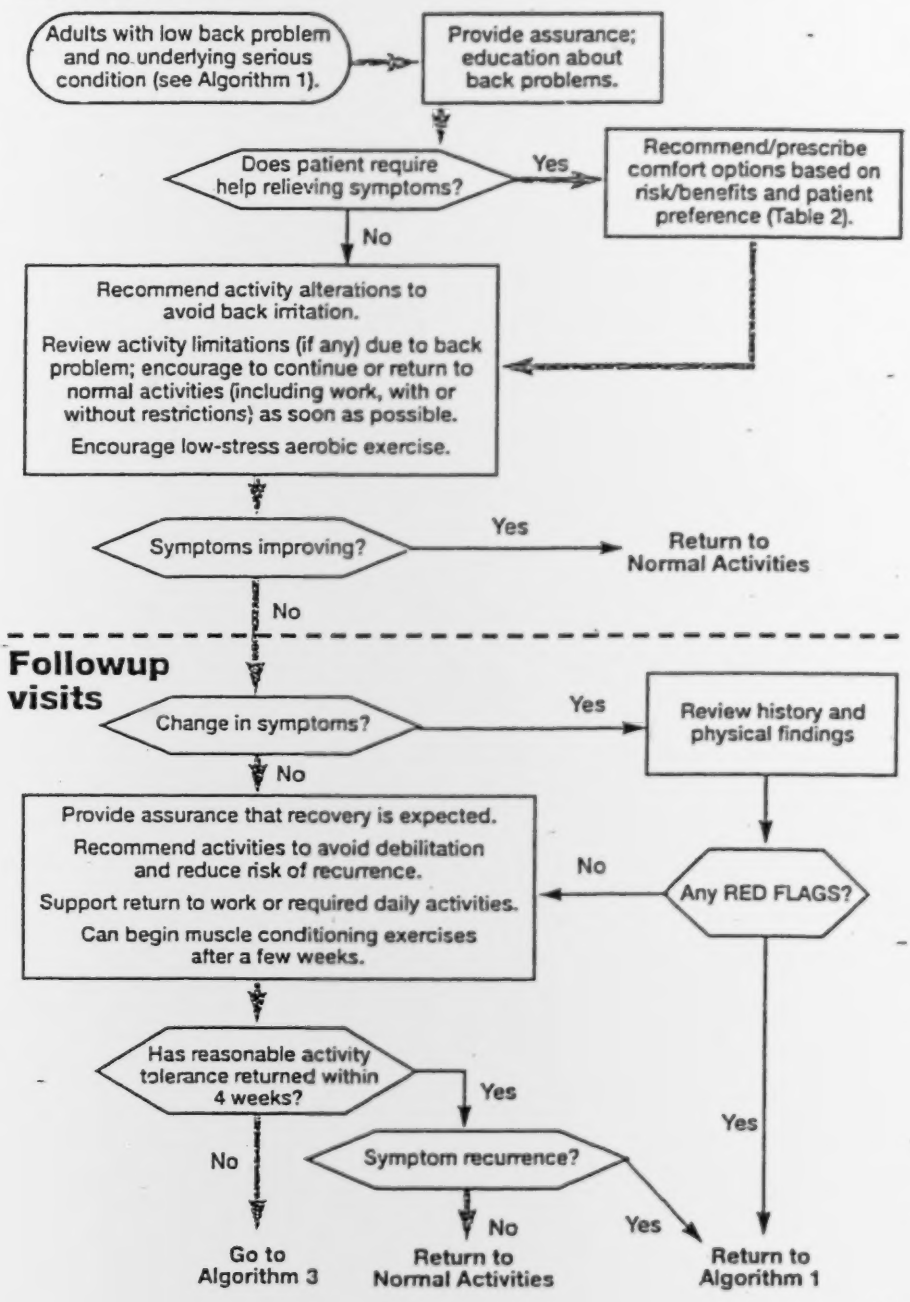
Algorithm 2. Treatment of acute low back problem on initial and followup visits



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Special Studies and Diagnostic Considerations

Routine testing (laboratory tests, plain x-rays of the lumbosacral spine) and imaging studies are not recommended during the first month of activity limitation due to back symptoms except when a red flag noted on history or examination raises suspicion of a dangerous low back or non-spinal condition. If a patient's limitations due to low back symptoms do not improve in 4 weeks, reassessment is recommended. After again reviewing the patient's activity limitations, history, and physical findings, the clinician may then consider further diagnostic studies, and discuss these with the patient.

Timing and Limits of Special Studies

Waiting 4 weeks before considering special tests allows 90 percent of patients to recover spontaneously and avoids unneeded procedures. This also reduces the potential confusion of falsely labeling age-related changes on imaging studies (commonly noted in patients older than 30 without back symptoms) as the cause of the acute symptoms. In the absence of either red flags or persistent activity limitations due to continuous limb symptoms, imaging studies (especially plain x-rays) rarely provide information that changes the clinical approach to the acute low back problem.

Selection of Special Studies

Prior to ordering imaging studies the clinician should have noted either of the following:

- The emergence of a red flag.
- Physiologic evidence of tissue insult or neurologic dysfunction.

Physiologic evidence may be in the form of definitive nerve findings on physical examination, electrodiagnostic studies (when evaluating sciatica), and a laboratory test or bone scan (when evaluating nonspecific low back symptoms). Unquestionable findings that identify specific nerve root compromise on the neurologic examination (see Figure 1) are sufficient physiologic evidence to warrant imaging. When the neurologic examination is less clear, however, further physiologic evidence of nerve root dysfunction should be considered before ordering an imaging study. Electromyography (EMG) including H-reflex tests may be useful to identify subtle focal neurologic dysfunction in patients with leg symptoms lasting longer than 3-4 weeks. Sensory evoked potentials (SEPs) may be added to the assessment if spinal stenosis or spinal cord myelopathy is suspected.

Laboratory tests such as erythrocyte sedimentation rate (ESR), complete blood count (CBC), and urinalysis (UA) can be useful to screen for nonspecific medical diseases (especially infection and tumor) of the low back. A bone scan can detect physiologic reactions to suspected spinal tumor, infection, or occult fracture.

Should physiologic evidence indicate tissue insult or nerve impairment, discuss with a consultant selection of an imaging test to define

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a potential anatomic cause (CT for bone, MRI for neural or other soft tissue). Anatomic definition is commonly needed to guide surgery or specific procedures. Selection of an imaging test should also take into consideration any patient allergies to contrast media (myelogram) or concerns about claustrophobia (MRI) and costs. A discussion with a specialist on selection of the most clinically valuable study can often assist the primary care clinician to avoid duplication. Table 4 provides a general comparison of the abilities of different techniques to identify physiologic insult and define anatomic defects. Missing from the table is discography, which is not recommended for assessing patients with acute low back symptoms.

In general, an imaging study may be an appropriate consideration for the patient whose limitations due to consistent symptoms have persisted for 1 month or more:

- When surgery is being considered for treatment of a specific detectable loss of neurologic function.
- To further evaluate potentially serious spinal pathology.

Reliance upon imaging studies alone to evaluate the source of low back symptoms, however, carries a significant risk of diagnostic confusion, given the possibility of falsely identifying a finding that was present before symptoms began.

Table 4. Ability of different techniques to identify and define pathology

Technique	Identify physiologic insult	Define anatomic defect
History	+	+
Physical examination:		
Circumference measurements	+	+
Reflexes	++	++
Straight leg raising (SLR)	++	+
Crossed SLR	+++	++
Motor	++	++
Sensory	++	++
Laboratory studies (ESR, CBC, UA)	++	0
Bone scan[1]	+++	++
EMG/SEP	+++	++
X-ray[1]	0	+
CT[1]	0	++++[2]
MRI	0	++++[2]
Myelo-CT[1]	0	++++[2]
Myelography[1]	0	++++[2]

[1]Risk of complications (radiation, infection, etc.): highest for myelo-CT, second highest for myelography, and relatively less risk for bone scan, x-ray, and CT.

[2]False-positive diagnostic findings in up to 30 percent of people without symptoms at age 30.

Note: Number of plus signs indicates relative ability to identify or define.

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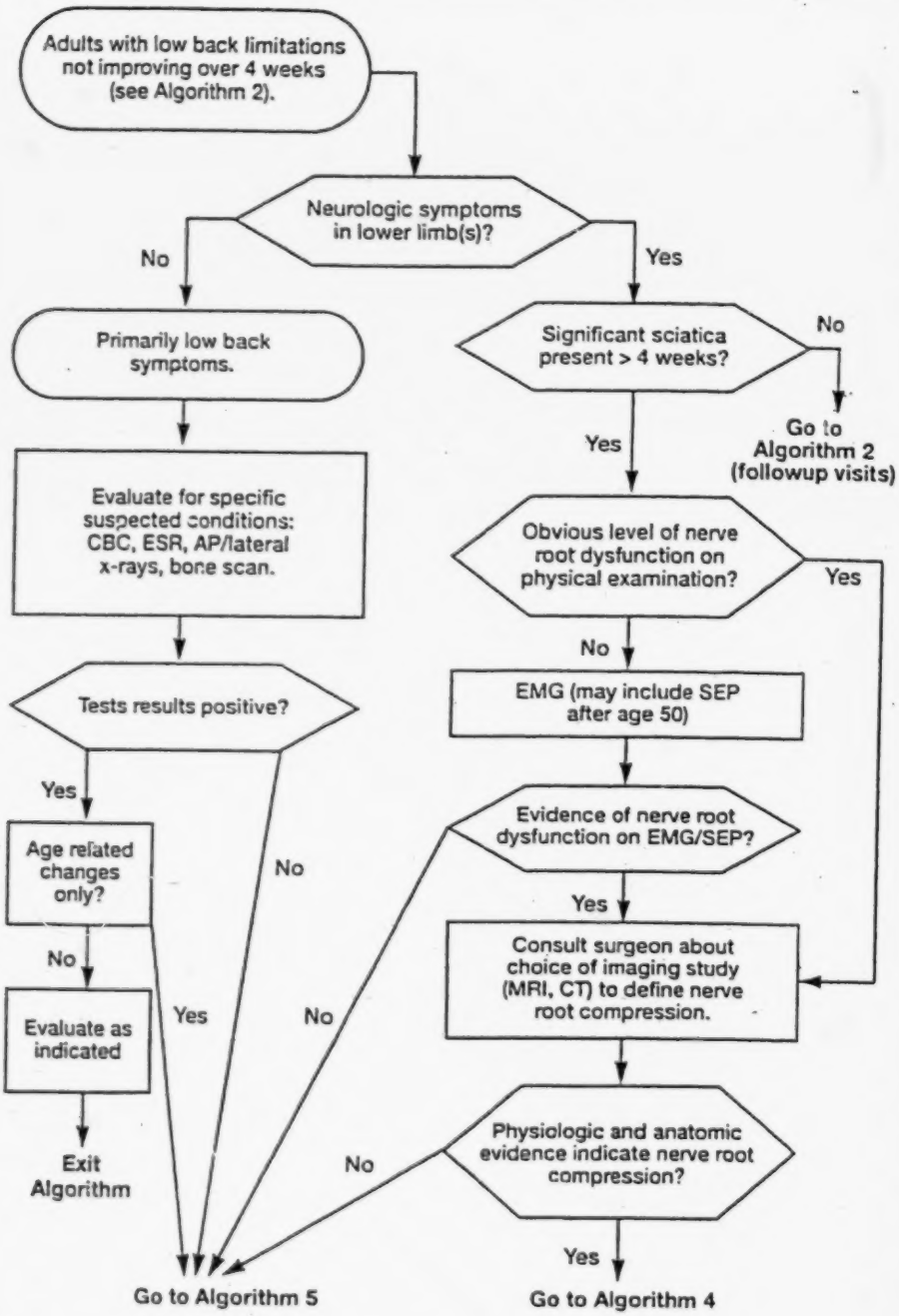
Algorithm 3. Evaluation of the slow-to-recover patient (symptoms > 4 weeks)



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Definitive treatment for serious conditions (see Table 1) detected by special studies is beyond the scope of this guideline. When special studies fail to define the exact cause of symptoms, however, no patient should receive an impression that the clinician thinks "nothing is wrong" or that the problem could be "in their head." Assure the patient that a clinical workup is highly successful in detecting serious conditions, but does not reveal the precise cause of most low back symptoms.

Surgical Considerations

Within the first 3 months of acute low back symptoms, surgery is considered only when serious spinal pathology or nerve root dysfunction obviously due to a herniated lumbar disc is detected. A disc herniation, characterized by protrusion of the central nucleus pulposus through a defect in the outer annulus fibrosis, may trap a nerve root causing irritation, leg symptoms and nerve root dysfunction. The presence of a herniated lumbar disc on an imaging study, however, does not necessarily imply nerve root dysfunction. Studies of asymptomatic adults commonly demonstrate intervertebral disc herniations that apparently do not entrap a nerve root or cause symptoms.

Therefore, nerve root decompression can be considered for a patient if all of the following criteria exist:

- Sciatica is both severe and disabling.
- Symptoms of sciatica persist without improvement for longer than 4 weeks or with extreme progression.
- There is strong physiologic evidence of dysfunction of a specific nerve root with intervertebral disc herniation confirmed at the corresponding level and side by findings on an imaging study.

Patients with acute low back pain alone, without findings of serious conditions or significant nerve root compression, rarely benefit from a surgical consultation.

Many patients with strong clinical findings of nerve root dysfunction due to disc herniation recover activity tolerance within 1 month; no evidence indicates that delaying surgery for this period worsens outcomes. With or without an operation, more than 80 percent of patients with obvious surgical indications eventually recover. Surgery seems to be a luxury for speeding recovery of patients with obvious surgical indications but benefits fewer than 40 percent of patients with questionable physiologic findings. Moreover, surgery increases the chance of future procedures with higher complication rates. Overall, the incidence of first-time disc surgery complications, including infection and bleeding, is less than 1 percent. The figure increases dramatically with older patients or repeated procedures.

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Direct and indirect nerve root decompression for herniated discs. Direct methods of nerve root decompression include laminotomy (expansion of the interlaminar space for access to the nerve root and the offending disc fragments), microdiscectomy (laminotomy using a microscope), and laminectomy (total removal of laminae). Methods of indirect nerve root decompression include chemonucleolysis, the injection of chymopapain or other enzymes to dissolve the inner disc. Such chemical treatment methods are less efficacious than standard or microdiscectomy and have rare but serious complications. Any of these methods is preferable to percutaneous discectomy (indirect, mechanical disc removal through a lateral disc puncture).

Management of spinal stenosis. Usually resulting from soft tissue and bony encroachment of the spinal canal and nerve roots, spinal stenosis typically has a gradual onset and begins in older adults. It is characterized by nonspecific limb symptoms, called ***neurogenic claudication*** or ***pseudoclaudication,*** that interfere with the duration of comfortable standing and walking. The symptoms are commonly bilateral and rarely associated with strong focal findings on examination. Neurogenic claudication, however, can be confused or coexist with ***vascular claudication,*** in which leg pain also limits walking. The symptoms of vascular insufficiency can be relieved by simply standing still while relief of neurogenic claudication symptoms usually require the patient to flex the lumbar spine or sit.

The surgical treatment for spinal stenosis is usually complete laminectomy for posterior decompression. Offending soft tissue and osteophytes that encroach upon nerve roots in the central spinal canal and foramen are removed. Fusion may be considered to stabilize a degenerative spondylolisthesis with motion between the slipped vertebra and adjacent vertebrae. Elderly patients with spinal stenosis who tolerate their daily activities usually need no surgery unless they develop new signs of bowel or bladder dysfunction. Decisions on treatment should take into account the patient's preference, lifestyle, other medical problems, and risks of surgery. Surgery for spinal stenosis is rarely considered in the first 3 months of symptoms.

Except for cases of trauma-related spinal fracture or dislocation, fusion alone is not usually considered in the first 3 months following onset of low back symptoms.

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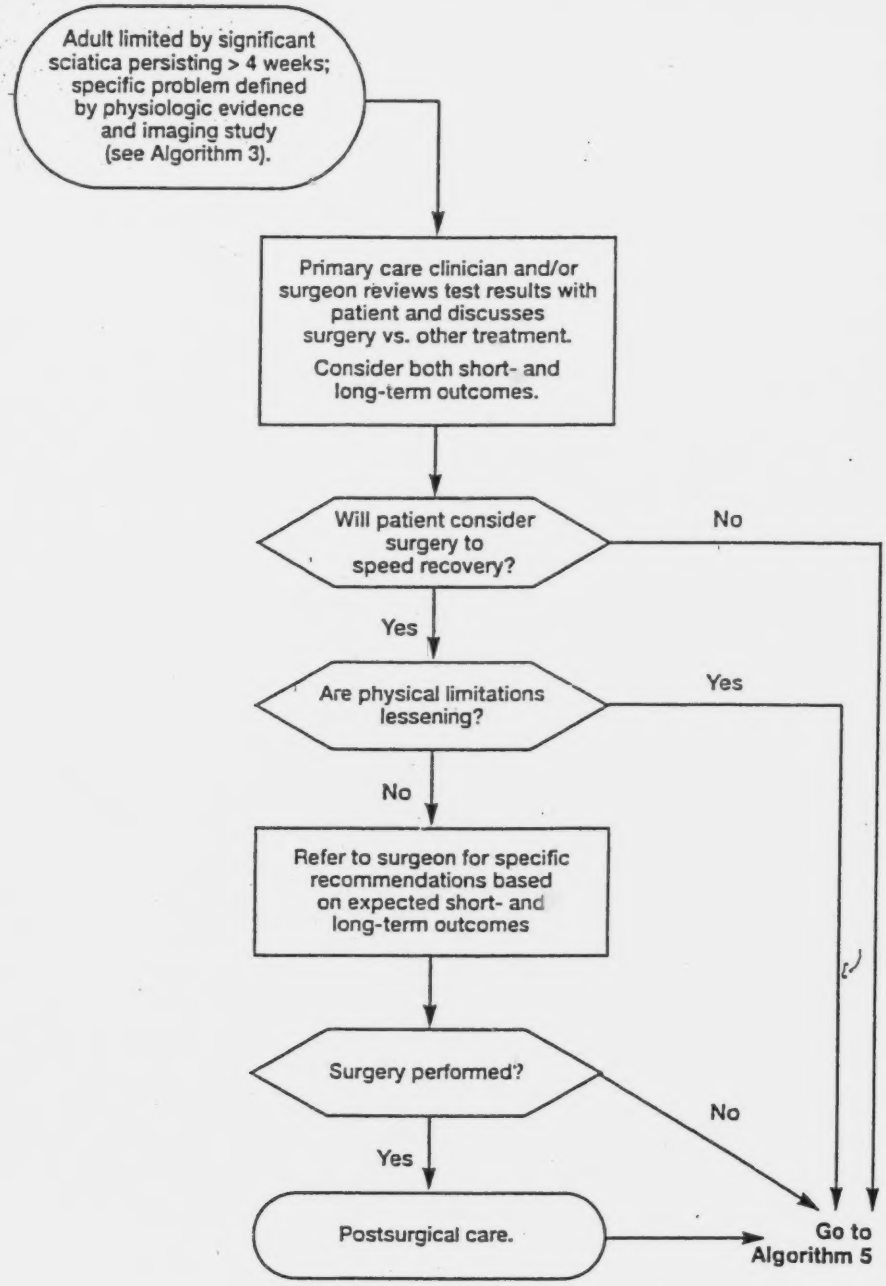
Algorithm 4. Surgical considerations for patients with persistent sciatica



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Further Management Considerations

Following diagnostic or surgical procedures, the management of most patients becomes focused on improving physical conditioning through an incrementally increased exercise program. The goal of this program is to build activity tolerance and overcome individual limitations due to back symptoms. At this point in treatment, symptom control methods are only an adjunct to making prescribed exercises more tolerable.

- Begin with low-stress aerobic activities to improve general stamina (walking, riding a bicycle, swimming, and eventually jogging).
- Exercises to condition specific trunk muscles can be added a few weeks after. The back muscles may need to be in better condition than before the problem occurred. Otherwise, the back may continue to be painful and easily irritated by even mild activity. Following back surgery, recovery of activity tolerance may be delayed until protective muscles are conditioned well enough to compensate for any remaining structural changes.
- Finally, specific training to perform activities required at home or work can begin. The objective of this program is to increase the patient's tolerance in carrying out actual daily duties.

When patients demonstrate difficulty regaining the ability to tolerate the activities they are required (or would like) to do, the clinician may pose the following diagnostic and treatment questions:

- Could the patient have a serious, undetected medical condition? A careful review of the medical history and physical examination is warranted.
- Are the patient's activity goals realistic? Exploring briefly the patient's expectations, both short- and long-term, of being able to perform specific activities at home, work, or recreation may help the patient assess whether such activity levels are actually achievable.
- If for any reason the achievement of activity goals seems unlikely, what are the patient's remaining options? To answer this question, the patient is often required to gather specific information from family, friends, employers, or others. If, on followup visits, the patient has made no effort to gather such information, the clinician has the opportunity to point out that low back symptoms alone rarely prevent a patient from addressing questions so important to his or her future. This observation can lead to an open, nonjudgmental discussion of common but complicated psychosocial problems or other issues that often can interfere with a patient's recovery from low back problems. The clinician can then help the patient address or arrange further evaluation of any specific problem limiting the patient's progress. This can usually be accomplished as the patient continues, with the clinician's encouragement, to build activity tolerance through safe, simple exercises.

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Algorithm 5. Further management of acute low back problem

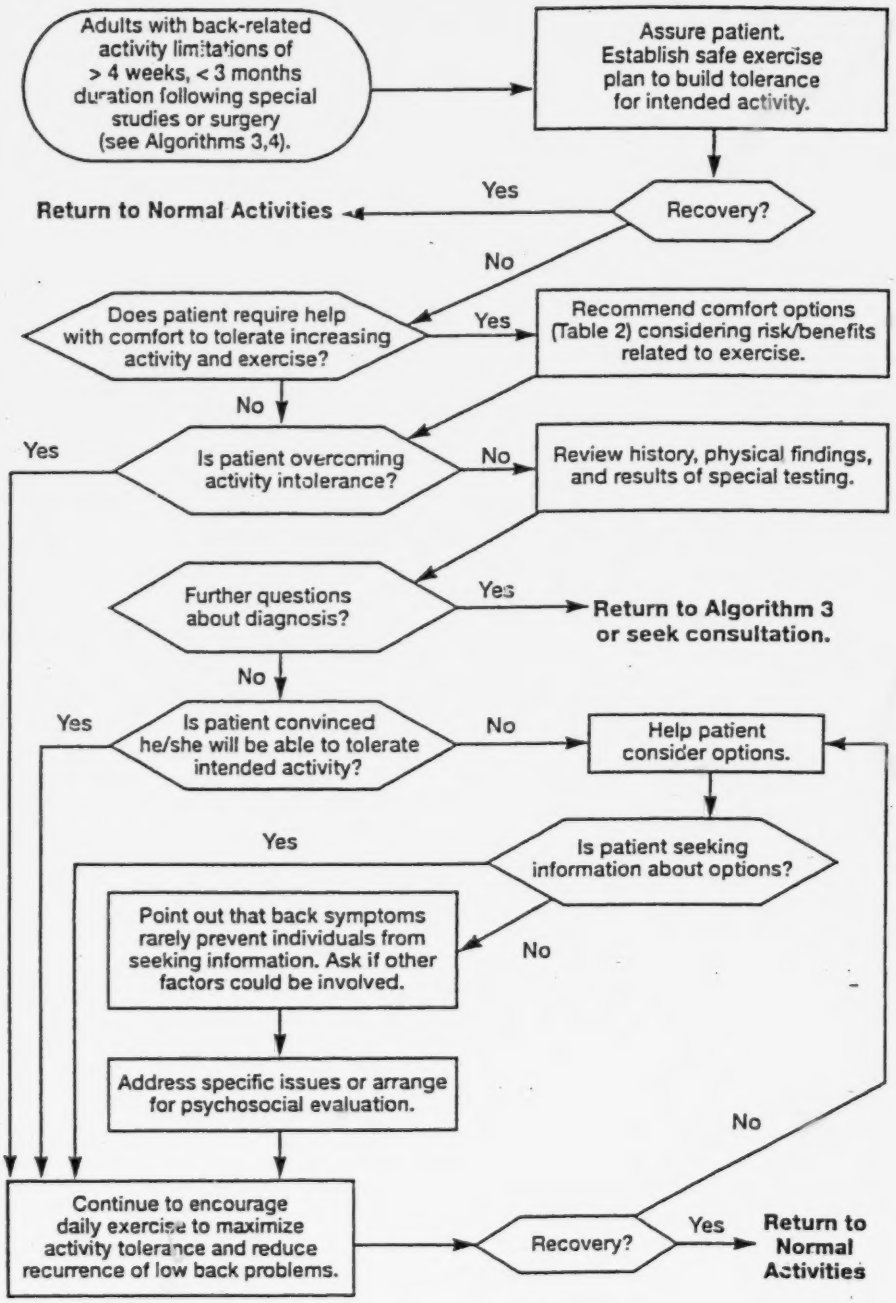

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Table 5. Summary of Guideline Recommendations

The ratings in parentheses indicate the scientific evidence supporting each recommendation according to the following scale:

A = strong research-based evidence (multiple relevant and high-quality scientific studies).

B = moderate research-based evidence (one relevant, high-quality scientific study or multiple adequate scientific studies).

C = limited research-based evidence (at least one adequate scientific study in patients with low back pain).

D = panel interpretation of evidence not meeting inclusion criteria for research-based evidence.

The number of studies meeting panel review criteria is noted for each category.

	Recommend	Option	Recommend against
History and physical exam 34 studies	Basic history (B). History of cancer/ infection (B). Signs/symptoms of cauda equina syndrome (C). History of significant trauma (C). Psychosocial history (C). Straight leg raising test (B). Focused neurological exam (B).	Pain drawing and visual analog scale(D).	
Patient education 14 studies	Patient education about low back symptoms (B). Back school in occupational settings (C).	Back school in non-occupational settings (C).	
Medication 23 studies	Acetaminophen (C). NSAIDs (B).	Muscle relaxants (C). Opioids, short course (C).	Opioids used >2 wks (C). Phenylbutazone (C). Oral steroids (C). Colchicine (B). Antidepressants (C).
Physical treatment methods 42 studies	Manipulation of low back during first month of symptoms (B).	Manipulation for patients with radiculopathy (C). Manipulation for patients with symptoms >1 month (C). Self-application of heat or cold to low back. Shoe insoles (C). Corset for prevention in occupational setting (C).	Manipulation for patients with undiagnosed neurologic deficits (D). Prolonged course of manipulation (D). Traction (B). TENS (C). Biofeedback (C). Shoe lifts (D). Corset for treatment (D).
Injections 26 studies		Epidural steroid injections for radicular pain to avoid surgery (C).	Epidural injections for back pain without radiculopathy (D). Trigger point injections (C). Ligamentous injections (C). Facet joint injections (C). Needle acupuncture (D).

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	Recommend	Option	Recommend against
Bed rest 4 studies		Bed rest of 2-4 days for severe radiulopathy (D).	Bed rest > 4 days (B).
Activities and exercise 20 studies	Temporary avoidance of activities that increase mechanical stress on spine (D). Gradual return to normal activities (B). Low-stress aerobic exercise (C). Conditioning exercises for trunk muscles after 2 weeks (C). Exercise quotas (C).		Back-specific exercise machines (D). Therapeutic stretching of back muscles (D).
Detection of physiologic abnormalities 14 studies	If no improvement after 1 month, consider: Bone scan (C). Needle EMG and H-reflex tests to clarify nerve root dysfunction (C). SEP to assess spinal stenosis (C).		EMG for clinically obvious radiculopathy (D). Surface EMG and F-wave tests (C). Thermography (C).
X-rays of L-S spine 18 studies	When red flags for fracture present (C). When red flags for cancer or infection present (C).		Routine use in first month of symptoms in absence of red flags (B). Routine oblique views (B).
Imaging 18 studies	CT or MRI when cauda equina, tumor, infection, or fracture strongly suspected (C). MRI test of choice for patients with prior back surgery (D). Assure quality criteria for imaging tests (B).	Myelography or CT-myelography for preoperative planning (D).	Use of imaging test before one month in absence red flags (B). Discography or CT-discography (C).
Surgical considerations 14 studies	Discuss surgical options with patients with persistent and severe sciatica and clinical evidence of nerve root compromise after 1 month of conservative therapy (B). Standard discectomy and microdiscectomy of similar efficacy in treatment of herniated disc (B). Chymopapain, used after ruling out allergic sensitivity, acceptable but less efficacious than discectomy to treat herniated disc (C).		Disc surgery in patients with back pain alone, no red flags, and no nerve root compression (D). Percutaneous discectomy less efficacious than chymopapain (C). Surgery for spinal stenosis within the first 3 months of symptoms (D). Stenosis surgery when justified by imaging test rather than patient's functional status (D). Spinal fusion during the first 3 months of symptoms in the absence of fracture, dislocation, complications of tumor or infection (C).
Psychosocial factors	Social, economic, and psychological factors can alter patient response to symptoms and treatment (D).		Referral for extensive evaluation/treatment prior to exploring patient expectations or psychosocial factors (D).

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Availability of Guidelines

For each clinical practice guideline developed under the sponsorship of the Agency for Health Care Policy and Research (AHCPR), several versions are produced to meet different needs.

The *Clinical Practice Guideline* presents recommendations for health care providers with brief supporting information, tables and figures, and pertinent references.

The *Quick Reference Guide for Clinicians* is a distilled version of the *Clinical Practice Guideline*, with summary points for ready reference on a day-to-day basis.

The *Consumer Version*, available in English and Spanish, is an information booklet for the general public to increase patient knowledge and involvement in health care decisionmaking.

To order single copies of guideline products or to obtain further information on their availability, call the AHCPR Publications Clearinghouse toll-free at 800-358-9295 or write to: AHCPR Publications Clearinghouse, P.O. Box 8547, Silver Spring, MD 20907.

Single copies of the *Clinical Practice Guideline* are available for sale from the Government Printing Office, Superintendent of Documents, Washington, DC 20402, with a 25-percent discount given for bulk orders of 100 copies of more. The *Quick Reference Guide for Clinicians* and the *Consumer Version* in English are also available for sale in bulk quantities only. Call (202) 512-1800 for price and ordering information.

The *Guideline Technical Report* contains complete supporting materials for the *Clinical Practice Guideline*, including background information, methodology, literature review, scientific evidence tables, recommendations for research, and a comprehensive bibliography. It is available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. Call (703) 487-4650 for price and ordering information.

The full text of guideline documents for online retrieval may be accessed through a free, electronic service from the National Library of Medicine called HSTAT (Health Services/Technology Assessment Text). Guideline information is also available through some of the computer-based information systems of the National Technical Information Service, professional associations, nonprofit organizations, and commercial enterprises.

A fact sheet describing Online Access for Clinical Practice Guidelines (AHCPR Publication No. 94-0075) and copies of the *Quick Reference Guide for Clinicians* and the *Consumer Version* of each guideline are available through AHCPR's InstantFAX, a fax-on-demand service that operates 24 hours a day, 7 days a week. AHCPR's InstantFAX is accessible to anyone using a facsimile machine equipped with a touchtone telephone handset: Dial (301) 594-2800, push "1," and then press the facsimile machine's start button for instructions and a list of currently available publications.

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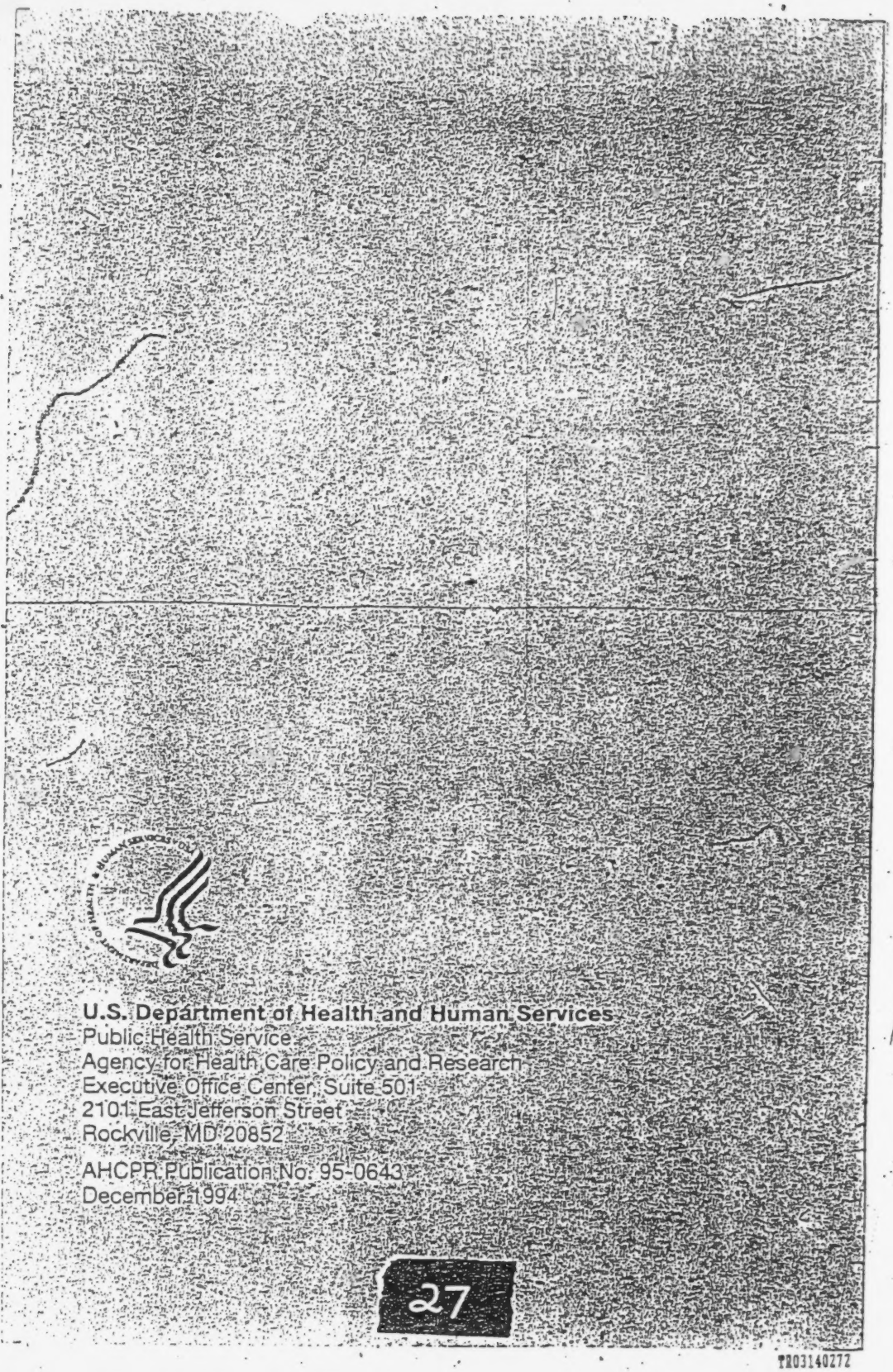

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Agency for Health Care Policy and Research
Executive Office Center, Suite 501
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Rockville, MD 20852

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Study of Pain Relief Backs Chiropractors

By Tom McNamee
Staff Writer

When it comes to lower back pain, think twice before resorting to the usual remedies—bed rest, prescription drugs and surgery.

Try a chiropractor instead.

The most effective treatment for acute lower back pain, according to a government report to be released today, is a combination of ordinary over-the-counter painkillers —such as Tylenol and aspirin—exercise and spinal manipulation.

The report, which has been circulating in draft form in the medical community, was written by the federal Agency for Health Care Policy and Research, and already is causing a stir. Some health care and physician groups are sniping hard at the report's conclusions, while chiropractors are cheering.

"This is the first time that the United States government has taken a position that is pro-chiropractic, and it is based upon research," said Dr. James Winterstein, president of the National College of Chiropractic in Lombard. "I'm proud of it. This is a watershed moment in our profession."

But the North American Spine Society, an organization whose membership is 70 percent orthopedic surgeons, stressed that the conclusions reached in the report are "untested" and "should serve only as a background" for doctors and patients. In any event, a spokesman for the society said, the report "should not directly dictate or limit" the care that individual patients receive.

Lower back pain is suffered, at one time or another, by up to 80 percent of adult Americans. Next to the common cold, it is the most common reason men and women visit primary care physicians.

The cost of that care is enormous. In 1990, the report says, at least $20 billion was spent on direct medical care for lower back pain. But as much as one-third of that money was "spent for services that did little to help patients." Add in the various indirect costs, such as lost work time and disability payments, and the cost approaches $50 billion.

Specifically, the report recommends the following treatment for lower back pain.

■ The use of acetaminophen (such as Tylenol), and nonsteroidal anti-inflammatory drugs like ibuprofen (such as Advil), naproxen (such as Aleve) and aspirin. Muscle relaxants, commonly prescribed by physicians, are an "option" for "short-term treatment," the authors add, but "appear to be no more effective" than the other medication.

■ Spinal manipulation by a chiropractor, osteopath or other therapist, especially in the first four weeks.

■ Low-stress exercise such as walking, swimming or biking, if the problems are "mild or moderate."

■ More rigorous "conditioning exercises" for the trunk muscles, to start and gradually increase after the first two weeks of pain.

But the report explicitly recommends against certain other common treatments, such as acupuncture, biofeedback and steroid pills, either because the treatment has not been proven effective, could have dangerous side effects or is not worth the money.

Resting in bed for more than four days, for example, could weaken muscles and bones and actually delay recovery, the report says. And spinal traction, another popular remedy, has not been proven successful.

The report discourages surgery within the first three months of the symptoms, unless there is clear evidence of a more serious underlying problem, such as a fracture of the spine. Surgery, the report says, appears to benefit only 1 percent of all people suffering lower back pain.

EXHIBIT
Vocopher 6
USSA 23-25

Los Angeles Times

Experts Push Low-Tech Care for Back Pain

BACK: Simple Care Pushed

By MARLENE CIMONS
TIMES STAFF WRITER

WASHINGTON—In a major departure from traditional practice, federal health officials said Thursday that the expensive tests and therapies typically used to diagnose and treat lower back pain are largely useless.

Instead they recommended over-the-counter pain medications, chiropractic and low-stress exercise, such as swimming or walking.

For most patients, symptoms will disappear on their own within a month, they said.

Acute lower back problems—pain or discomfort in the lower back or pain and numbness that moves down the leg (sciatica)—is a sometimes-debilitating condition suffered at some point by almost everyone.

In fact, after the common cold, it is the leading reason that people see their primary-care physicians, according to the federal government.

Back pain can occur at any point on the spine for no apparent reason, but it most commonly crops up in the lower back region because that area bears the majority of the body's weight.

Lower back pain can severely restrict an individual's activities, including the ability to work—sometimes for weeks. In 1990, more than $20 billion in direct medical costs was spent on the condition, mostly for diagnostic tests. The total annual cost—including lost productivity—is estimated at $50 billion.

The new guidelines were compiled by a panel of medical experts who reviewed nearly 4,000 studies. The group was convened by the federal Agency for Health Care Policy and Research, which released the recommendations that are expected to be regarded as the standard of care.

The panel did not address chronic lower back problems, which are the subject of ongoing studies. But it stressed that people with long-term problems represent fewer than 5% of those afflicted with lower back pain. This group may or may not include people with disk problems, depending on the extent or severity of their symptoms.

The guidelines will provide "new hope to those who are confused about the myriad of approaches to acute low back problems," said Dr. Stanley J. Bigos, chairman of the panel and a professor of orthopedic surgery at the University of Washington School of Medicine in Seattle.

The panel said the early use of tests such as X-rays, computed tomography and magnetic resonance imaging should be discouraged unless symptoms indicate more serious underlying conditions, such as fractures, tumors, infections or spinal nerve root problems.

Also, the usual therapies—extended bed rest, muscle relaxants and surgery—can be unnecessary and, in some cases, harmful, the panel said.

Resting in bed for more than four days "can weaken muscles and bones and delay recovery," the panel said.

Within the first three months of symptoms, surgery is only recommended for those with evidence of serious spinal problems or those with certain leg symptoms that result from nerve conditions, dislocations or fractures, the panel said. Surgery appears to benefit only about one out of 100 individuals with acute low back pain, the group said.

Instead, the group said the use of acetaminophen and non-steroidal anti-inflammatory drugs was safe and effective, as was walking, swimming or biking—activities that help maintain and build a patient's tolerance to physical activity.

Chiropractic, which uses spinal manipulation to ease pain, was also found to be helpful, especially within the first four weeks of the onset of pain, the panel said.

The recommendations were a significant validation to the century-old discipline of chiropractic, as well as a rebuff to surgeons.

For many years, chiropractic was the object of criticism and scorn from the medical Establishment, despite growing consumer support. In recent years, however, it has begun to enjoy increasing credibility within mainstream medicine.

Noting that spinal manipulation is a drug-free, non-surgical, low-cost form of relief, Dr. Lawrys Morton, chairman of the board of the American Chiropractic Assn., said he hoped the guidelines would encourage managed-care health plans and health maintenance organizations to include chiropractic within their coverage.

"Spinal manipulation is effective; it gets low back pain patients on their feet and back to work faster than any other form of care," he said.

The panel also recommended ways to prevent back pain. These include engaging in regular exercise; wearing comfortable, low-heeled shoes; using work surfaces at a comfortable height and chairs with good lower back support; and the use of lumbar corsets by people whose jobs require frequent lifting.

Also, when lifting, individuals should avoid twisting, bending and reaching, and keep objects close to the body, the panel said.

Health Information

• To hear more information about lower back pain, as well as other problems with muscles, bones and joints, call TimesLine at 808-8463 and press #5190.

Details on Times electronic services, B4

AP photo

front of his own portrait, PLO leader Yasser Arafat
pporters during a rally Thursday in the Gaza Strip.

'at's newest test: Fatherhood

o Press

CITY, Gaza—Yasser
going to be a father.
ife, Suha, announced
nancy in an interview
y with Israel Radio's
Service. Her spokes-
said Suha Arafat is one
egnant.
ll, who leaves for
on Friday to receive
el Peace Prize, got the
Prize and the baby."

It will be the first biological child for the 65-year-old Arafat and his wife. They also care for 38 war orphans Arafat brought out of Palestinian refugee camps in Lebanon in the 1980s.

Suha Arafat, was Arafat's secretary before their marriage in November 1991. The marriage was kept secret for 15 months.

Arafat leaves Friday for Oslo,

Government's approved Rx for back pain: Take a hike

Associated Press

WASHINGTON—Chiropractors get a boost and surgeons a setback in new, government-backed guidelines on how to treat low back pain. For most sufferers, they say, problems will go away on their own within a month.

In the interim, the experts said Thursday, the best advice is to spend no more than two or three days in bed, take over-the-counter painkillers and start moderate, low-stress exercise such as walking or swimming as soon as possible.

The new guidelines for acute low back pain frown on surgery and a host of high-cost tests—including X-rays, CT scans and magnetic resonance imaging—and dismiss as unproven such treatments as spinal traction, biofeedback, transcutaneous electrical nerve stimulation, acupuncture, steroids and injections.

But it says that spinal manipulation, usually performed by a chiropractor, "can be helpful for patients with acute low back problems ... within the first month of symptoms."

Up to 20 percent of adults suffer lower back problems each year, and four out of five will experience-the-agonizing-problem-at least once before their 50th birthday.

The new guidelines offer back sufferers reassurance that "there are safe, effective 'low-tech' ways to feel better and get back to regular activities while your back heals on its own," said Philip Lee, the assistant secretary for health and head of the Public Health Service.

Dr. Stanley Bigos, professor of orthopedic surgery at the University of Washington School of Medicine in Seattle and chairman of the 23-member panel of experts, said the guidelines offer "new hope to those who are confused about the myriad of approaches to acute low back problems."

Too often in the past, Bigos said, doctors have sent patients to bed for extended periods, given them "disorienting painkillers" and ordered "needless, confusing tests."

The experts said surgery helps only 1 in 100 people with sudden back problems. Extensive diagnostic tests are in order only for those patients a doctor suspects might have a fracture, a tumor, an infection or severe nerve involvement.

The guidelines state, "Even having a lot of back pain does not by itself mean you need surgery."

For 9 out of 10 adults, the back problem will go away spontaneously within four weeks.

An ice pack applied to the painful area for five or 10 minutes may help in the first 48 hours. Beyond that, a heating pad or hot shower or bath may work.

For pain relief, acetaminophen or the nonsteroidal anti-inflammatory drugs—aspirin, ibuprofen and naproxen—work just as well as muscle-relaxants or prescription painkillers and are safer.

The experts reviewed more than 3,000 studies in preparing the guidelines for the U.S. Agency for Health Care Policy and Research.

The guidelines do not address chronic back problems.

Controversial atom bomb stamp scrapped

Associated Press

WASHINGTON—The post office, under heavy White House and diplomatic pressure, is scrapping plans for a stamp recalling the atomic bombing of Japan.

"We are changing the design of the stamp because of the importance of U.S.-Japan relations at this critical time in U.S. foreign policy, and because President Clinton conveyed his views that it was appropriate to do so," Postmaster General Marvin Runyon said Thursday.

The stamp—which was to depict a mushroom cloud following a bomb blast—will be replaced by a design showing President Truman preparing to announce the end of

cials were outraged over the design and filed protests.

The Postal Service initially defended the stamp as commemorating a crucial event in the war that needed to be part of the series of World War II stamps spread over several years.

Runyon said he was particularly mindful of the feelings of veterans—who make up a large part of the postal work force. "Many gave their lives for their country, and we will always be grateful for their paying the ultimate price," Runyon said.

The post office's governing board discussed the controversy at a closed meeting recently and directed Runyon not to change the stamp unless Clinton called for

White House press secretary Dee Dee Myers had commented Wednesday that while the atomic bomb helped speed the end of the war, "there could be more appropriate ways to depict that event."

The State Department had also pointedly urged that the stamp be dropped.

Postal spokesman Robin Wright, releasing Runyon's announcement, said the agency does not want to do anything that would affect the friendship between the U.S. and Japan.

"We believe the long-term interests of the United States are best served by eliminating sore spots when possible," Wright said.

And retired Maj. Gen. Charles W. Sweeney, the pilot of the plane

Nation/World

Army, A

Associated Press

WASHINGTON—The A
Air Force announced
reductions Thursday tha
lens of thousands from
tary's uniformed and
ranks over the next two

The Army will go fror
active-duty divisions
thousands more positi
the support ranks for a
tion of about 10 percen
next 19 months. Army
fall most heavily on Kan
rado and Texas.

An Air Force plan call

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Stainless steel ca
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Weather

The Washington Post

FINAL

116th Year — No. 4 — FRIDAY, DECEMBER 9, 1994 — 25¢

Barry Plan to Cut $431 Million Targets Police, Schools, Salaries

By Yolanda Woodlee
Washington Post Staff Writer

D.C. Mayor-elect Marion Barry yesterday announced a detailed and wide-ranging economy program for the city to save and generate, starting in fiscal 1995, $431 million in cuts and other measures to help close the District's budget gap for the remainder of fiscal 1995 and for the next five years.

Addressing the District's financial future at a meeting of the City Council, Barry said that he hopes to restore funds eventually for the $431 million that will be cut from the budget, but added that even those cuts will fall short of the $700 million deficit he has estimated the city will face in fiscal 1996.

The package of cuts and revenue increases he unveils the District is close to avoid going broke, but he said it may overlook the 100 layoffs, mid-level officers, from 631 million from the police, schools, and overhead reductions in the plan for $53 million, he does the number of city police officers and cut the number of beds at D.C. General hospital by 50 percent.

The Barry administration has already begun to implement some of the cuts and revenue increases, such as those pertaining to the city's budget. Barry said he will not raise taxes and will not lay off any more workers than he has already announced.

Barry said he is confident that the city will be able to avoid any additional layoffs.

But he cautioned, though, that even if the D.C. Council agrees with all his proposals—some of which lawmakers already have promised to—the city will still be $96 million in the red.

"We will have to do more," Barry said at a briefing at the Dan A. Wilson Building yesterday. "We have to meet Wall Street that we're serious about this.

"I'm not going to run the budget out of existence for inefficiency and ineffective city government," he said. "We're going to make D.C. government more effective, more efficient and more responsive. We're not going to say, 'Well, there we go again.' We can't do that. We're going to do something with the whole budget."

Barry's plan follows previous cutting proposals put forth by outgoing Mayor Sharon Pratt Kelly and Council Chairman David A. Clarke (D) but considered to be the most aggressive yet. Kelly wanted to cut $140 million, and Clarke proposed a plan that would have saved $200 million. Barry's package of $431 million in reductions is made up of the city's $53.2 billion general fund.

The administrative elements of Barry's management restructuring will be presented to the city board meeting on D.C. Council chairman Clarke said that the city needs to narrow the gap between cuts and tax increases to $200 million. Barry's package of $431 million in reductions is made up of the city's $3.2 billion general fund.

The administrative elements of Barry's management restructuring will be presented to the city board meeting on D.C. Council chairman Clarke said that the city needs to narrow the gap between cuts and tax increases to $200 million. Barry's package of $431 million in reductions is made up of the city's $3.2 billion general fund.

See DISTRICT, A10, Col. 1

White House Considers Cutting a Cabinet Agency

Aides Prepare Dramatically Slashed Budget

By Ann Devroy and Jonathan Barr
Washington Post Staff Writers

President Clinton's senior economic and political advisers are preparing budget options that would dramatically slash departments and lead-pipe cinch eliminate a Cabinet department, as the White House, operating with the new Republican Congress in mind, looks for ways to streamline government.

A senior official said last night that while the options include eliminating departments such as Housing and Urban Development and Energy, officials are more concerned with "serious, significant, major restructurings" rather than performing a demolition job.

Republicans, who control the House and Senate, have already said that they intend to do away with the Department of Energy in the fiscal 1996 budget Clinton is preparing to submit to Congress in February. The White House has made clear that it will fight to preserve HUD, which considered a prime candidate for elimination because it has been Henry Cisneros has produced a workable set of proposals that call for "downsizing, reengineering" and "program mission."

See OPTIONS, A18, Col. 5

CAP hears a dissent plan on environmental law. Page 1A

Leaders of Clinton's environmental community. Page 1A

Down Go the Prices, Up Go Eyebrows

Retailers Fight for Yule Sales With Unreasonably Sharp Discounts

By Kenneth Dennis Gonzalez
Washington Post Staff Writer

This holiday season is shaping up as a Grateful Age for consumers, according to retailers, industry analysts and shoppers, who are getting big bargains as a result of prices being slashed in a brutally competitive marketplace.

Retailers have slimmed their costs, maintained their inventories and slashed their prices to respond to today's sophisticated consumers, who have become accustomed to one-of-a-kind prices at wholesale clubs and discount stores, catalogs and airplane seats.

Many shoppers say savoring the experience. As Steven Tanning, a City Place shopping center bar consultant, Lisa C. Crawford, 28, an AT&T employee, purchased the latest line of a mid-range coat offered for $89.99. "You couldn't have found it two years ago at that price," Crawford said, adding that such promotions and sales prices appeal to her because standard prices seem too unreasonable and discounts tend to get more for her dollar.

In a survey of 500 consumers conducted by the Chain Store Age Executive magazine, more than 24,000 stores nationwide, conducted by the Shopper Trak RTM, Mitch Retail Information Corp., Inc., said their sales had increased their prices, and 39 of the 48 said their sales had also risen since 1992 levels. Only three of the 39 said there were unchanged their prices, while seven said their pricing strategy has varied between sales and rack.

Large local retailers are reporting the same trend. Mark Cohen, the manager, which has 42 stores in the Washington area, said prices for photographic chose

See PRICES, A18, Col. 1

U.S. to Send Forces if U.N. Quits Bosnia

Ground Troops Would Help in Evacuation

By Ann Devroy and Bradley Graham
Washington Post Staff Writers

The Clinton administration has made clear that NATO allies and congressional leaders that if it would, provided America ground troops to help evacuate United Nations peacekeeping forces from Bosnia if it withdrawal is requested, U.S. officials said.

The administration position, presented by Clinton and his principal foreign policy advisers, is intended to head off a growing movement in Congress to withdraw U.N. forces from Bosnia, arming the Bosnian government and perhaps using air power against Serbian forces. Some administration officials said the Bosnian government officials said.

Some administration officials said President Clinton had decided on the move. However, as the recommendation of his senior advisers. The decision followed several days of discussions among top U.S. military and civilian officials, who said change of U.N. forces were undertaken.

In both cases, officials said, the administration would remain in the policy it pursued early last year, pressing for a lifting of the arms embargo against the Bosnian Muslims while discouraging aggressive withdrawal of the European forces involved.

See TROOPS, A18, Col. 1

The Class With Clout

GOP House Freshmen Are Young, Driven

By Karen Tumulty and Kenneth J. Cooper
Washington Post Staff Writers

Though their united determination as a class sure caught Democratic leaders off guard, the newly ascendant Republicans in the House of Representatives are not a monolith. Some are fiscal conservatives who want to balance the budget, others are more concerned with social issues. Some are willing to work with the Democrats, others are not.

"There are folks who can run it, let bubbles, and I suspect," said Rep. Steve Stockman (R-Texas), "that there are the message of tomorrow and that the responsibility is to have one to keep the opportunity. I sensed a danger myself in the big groups. But as a general proposition this is a very conservative group. I think I have very mainstream views. This is really an experiment, across ground of people, and that's our goals and objectives."

The class of '94 is younger and more ideologically—range narrower than the class of '92, with fewer

See FRESHMEN, A18, Col. 1

Back Pain? You Can't Take It Lying Down Anymore

By Sandy Rovner
Washington Post Health Writer

Treating medical problems, a subject of much controversy, is the subject of much controversy, is the subject of much controversy, is the

BY MARY LOU FOY—THE WASHINGTON POST

"You couldn't have found it two years ago at that price," says Lisa C. Crawford of a low-priced coffee machine.

Down Go the Prices, Up Go Eyebrows

Retailers Fight for Yule Sales With Unseasonably Sharp Discounts

By Kirstin Downey Grimsley
Washington Post Staff Writer

This holiday season is shaping up as a Golden Age for consumers, according to retailers, industry analysts and shoppers who say prices for many goods are steady or even falling because of a bruisingly competitive marketplace.

Retailers have trimmed their costs, restructured their businesses and slashed their prices to appeal to today's tightfisted consumers, who have become accustomed to warehouse-type prices at wholesale clubs and discount stores, retailers and analysts said.

Many shoppers are sensing the opportunity. At Silver Spring's City Place shopping center, for example, Lisa C. Crawford, 38, an AT&T executive, gestured the other day at a mini-espresso coffee machine being offered for $59.99. "You couldn't have found it two years ago at that price," Crawford said, adding that such promotional and sales prices appear to be driving standard prices down for consumers and allowing her to get more for her dollar.

In a survey of 50 retailers representing more than 24,000 stores nationwide, conducted by the Bloomfield Hills, Mich.-based Taubman Centers Inc., 40 said they have not increased their prices, and 20 of the 40 said they have cut them below 1993 levels. Only three of the 50 said they have increased their prices, while seven said their pricing strategy was mixed between hikes and cuts.

Large local retailers are reporting the same trend. Ritz Camera, for example, which has 43 stores in the Washington area, said prices for photography equip-

See PRICES, A10, Col. 1

...round Troops Would Help in Evacuation

By Ann Devroy and Bradley Graham
Washington Post Staff Writers

The Clinton administration formally notified NATO allies and congressional leaders yesterday that it would provide American ground troops to help evacuate United Nations peacekeeping forces from Bosnia if a withdrawal is requested, U.S. officials said.

The commitment involves providing about half the evacuation protection force, meaning from 5,000 to 25,000 U.S. troops. A withdrawal would be a highly complex and potentially very dangerous operation for allied forces given Bosnia's mountainous terrain, wide dispersal of U.N. forces and unremitting warfare between separatist Serbs and the Muslim-led government, officials said.

Senior administration officials said President Clinton had decided on the move Tuesday, at the recommendation of his senior advisers. The decision followed several days of discussions about how U.S. policy toward Bosnia would change if U.N. forces were withdrawn.

In such a case, officials said, the administration would return to the policy it pursued early last year, pressing for a lifting of the arms embargo against the Bosnian Muslims while threatening aggressive airstrikes if the Bosnian Serbs attacked

See TROOPS, A41, Col. 1

Back Pain? You Can't Take It Lying Down Anymore

By Sandy Rovner
Special to The Washington Post

Toppling medical tradition, a panel of medical experts yesterday threw out bed rest and endorsed exercise and spinal manipulation as treatments with proven effectiveness for episodes of acute lower back pain.

The recommendations are part of new government guidelines for treating the most common cause of disability in Americans under the age of 45. To determine which measures have been shown to work for lower back pain, the government-appointed panel evaluated more than 3,900 studies on treatments ranging from spinal fusion surgery to acupuncture. It found that there was no solid scientific evidence to support the use of many popular remedies.

The guidelines were produced by the Agency for Health Care Policy and Research, part of the Department of Health and Human Services. They deal only with the treatment of lower back pain episodes—those that resolve within a month, although they may recur over and over. The guidelines did not consider chronic back pain, which is diagnosed when episodes last three months or longer.

The panel concluded that bed rest probably did more harm than good, and that no data supported the use of biofeedback or acupuncture for back pain. On the other hand, it found that spinal manipulation—a treatment often performed by chiropractors and osteopaths—was safe and effective for patients within the first month of symptoms from an episode of uncomplicated lower back pain.

Many doctors have long discouraged their patients from trying such treatments.

Because nine out of 10 episodes of acute back pain improve on their own within a few weeks, no painkillers stronger than acetamino-

See BACK, A4, Col. 2

e to Colorado: $120,000

Runs Into Flak on Hill (But the Cat Paid)

...ent at the time, but it is causing trouble now.

...fter a complaint from Capitol ..., Defense Department Acting In...ctor General Derek J. Vander...aaf agreed this week to investi...e the propriety of the flight and ...ther Air Force public affairs per...nel were truthful in answering ...cters' inquiries.

...ahy, who followed Pentagon reg...ions by paying $85 fare for the ... declined to comment.

... spokesman at the Space Com...d in Colorado Springs, Lt. Col. ...nis Gauci, said Ashy and his aide ...idered flying a commercial flight out of Rome on Sept. 10, but worried the schedule would not give him enough time in Colorado the next day to take an eight-hour training course on procedures for alerting the president in event of an air attack.

He was sworn in as head of the Space Command Sept. 13.

Ashy, 54, a 32-year Air Force veteran and fighter pilot, could not leave earlier, the Air Force said, because he was still commander of the 16th Air Force in Italy, a job that included directing air missions over Bosnia.

See FLIGHT, A10, Col. 1

INSIDE

No Apologies
■ Jesse L. Jackson refused to apologize for remarks in which he called the Christian Coalition a "strong force" in Nazi Germany and a racist influence in the slave-holding South.
NATION, *Page A2*

Cubans Riot
■ A thousand Cuban refugees threw stones at U.S. soldiers, then fled their camps in Panama. Almost all were captured, but about 230 GIs suffered minor injuries.
WORLD, *Page A37*

SEC Trading Suit
■ The Securities and Exchange Commission yesterday accused two top executives of Rosslyn-based Gannett Co. and the chairman of a major Washington construction company of insider trading. Two of the executives settled the allegations.
BUSINESS, *Page F1*

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NATIONAL HEALTH EXPENDITURES BY TYPE OF SERVICE AND SOURCE OF FUNDS: CALENDAR YEARS 1960-02

LEVELS in $Millions	2002	2001	2000	1999	1998	1997	1996	1995	1994	1993	1992	1991
National Health Expenditures	1,553,009	1,420,688	1,309,444	1,222,602	1,150,308	1,092,784	1,039,343	990,221	937,150	888,063	827,043	761,826
Private Funds	839,573	768,383	714,857	669,713	628,961	589,227	556,847	533,603	509,709	497,703	468,520	441,260
Consumer Payments	762,082	696,088	641,913	597,145	558,185	522,186	495,663	476,230	455,476	445,026	419,760	396,032
Out-of-pocket Payments	212,510	200,529	192,564	184,475	175,305	162,065	151,884	146,486	143,790	146,948	145,923	142,133
Pvt Health Insurance	549,572	495,559	449,349	412,671	382,880	360,120	343,779	329,744	311,686	298,078	273,837	253,899
Other Private Funds	77,492	72,295	72,944	72,568	70,777	67,042	61,184	57,373	54,232	52,678	48,760	45,228
Industrial Inplant	4,653	4,443	4,238	3,963	3,776	3,605	3,427	3,259	3,057	2,840	2,627	2,427
Privately funded const	16,035	13,714	13,276	12,445	12,686	12,459	10,835	10,346	11,284	11,490	10,565	9,719
Other Private Revenues Including Philan.	56,803	54,137	55,429	56,160	54,314	50,977	46,921	43,768	39,892	38,348	35,567	33,082
Public Funds	713,436	652,305	594,586	552,888	521,347	503,557	482,496	456,618	427,441	390,360	358,523	320,565
Federal Funds	504,717	460,274	415,951	386,442	368,429	360,155	344,836	322,393	298,934	274,373	251,113	221,678
Medicare	267,105	246,500	225,055	213,513	210,247	209,538	198,347	183,097	166,321	148,336	136,298	120,913
Workers' Compensation	732	706	663	601	572	565	561	568	600	600	575	530
Public Assistance	150,477	134,159	119,703	109,056	99,800	94,837	92,127	86,177	81,299	76,762	67,957	56,694
Medicaid (Title XIX)	146,558	131,142	117,644	107,945	99,562	94,837	92,127	86,177	81,299	76,762	67,957	56,694
Medicaid SCHIP Expa	989	883	753	434	111	0	0	0	0	0	0	0
SCHIP (Title XXI)	2,930	2,134	1,306	677	128	0	0	0	0	0	0	0
Non-XIX Federal	0	0	0	0	0	0	0	0	0	0	0	0
Department of Defense	17,238	15,204	13,952	12,878	12,246	12,082	11,952	12,059	11,819	12,053	11,593	11,564
Maternal/Child Health	626	612	608	605	586	581	580	587	594	578	566	517
Veterans' Administration	22,255	21,713	19,096	17,657	16,930	16,334	16,261	15,410	15,121	14,140	13,063	12,241
Vocational Rehabilitation	641	621	594	576	570	563	525	529	521	464	478	452
General Hospital/Medical	0	0	0	0	0	0	0	0	0	0	0	0
Gen Hosp/Med NEC	5,441	5,097	4,372	3,917	3,308	3,035	2,726	2,458	2,391	2,174	1,975	1,772
ADAMHA/SAMHSA	2,972	2,774	2,637	2,420	1,996	1,500	1,783	2,067	1,889	1,714	1,685	1,656
Indian Health Services	1,934	1,905	1,757	1,616	1,560	1,570	1,467	1,520	1,361	1,379	1,349	1,127
O.E.O.	0	0	0	0	0	0	0	0	0	0	0	0
Public Health Activity	7,041	5,298	4,847	4,525	4,030	3,924	3,753	3,650	3,626	3,144	2,914	2,595
Research	27,419	24,984	21,906	18,195	15,543	14,338	13,563	13,199	12,510	12,094	11,876	10,890
Construction	835	700	761	882	1,040	1,287	1,192	1,072	882	935	784	726
State and Local Funds	208,719	192,031	178,636	166,446	152,918	143,403	137,660	134,225	128,507	115,987	107,409	98,887

Temporary Disability	49	50	48	49	54	58	54	52	53	52	70	66
Workers' Compensation	29,281	26,943	24,667	22,180	20,142	19,984	21,345	21,346	21,562	21,025	20,524	18,428
Public Assistance	109,120	98,042	89,595	82,641	76,842	69,858	65,447	63,298	57,900	49,886	45,761	41,733
Medicaid (Title XIX)	102,489	91,873	84,715	78,282	71,808	64,691	60,033	57,861	52,449	44,849	40,230	36,546
Medicaid SCHIP Expa	399	355	293	166	43	0	0	0	0	0	0	0
SCHIP (Title XXI)	1,286	950	603	324	64	0	0	0	0	0	0	0
Non-XIX State/Local	0	0	0	0	0	0	0	0	0	0	0	0
General Assistance	4,945	4,864	3,983	3,869	4,928	5,167	5,414	5,437	5,451	5,037	5,531	5,187
Maternal/Child Health	2,185	2,148	2,068	2,003	1,832	1,764	1,683	1,625	1,568	1,504	1,465	1,430
Vocational Rehabilitation	202	203	192	189	186	183	180	177	173	155	144	132
St/L Hosp + School Hlth	15,177	14,005	13,372	13,730	13,757	13,341	13,515	14,107	15,300	14,185	12,733	13,070
Public Health Activity	44,118	43,027	40,969	39,202	33,967	31,515	29,164	27,781	26,382	24,075	21,931	19,852
Research	4,197	3,820	3,469	3,081	3,017	2,792	2,661	2,496	2,298	2,119	1,988	1,890
Construction	4,390	3,792	4,254	3,370	3,121	3,908	3,611	3,344	3,271	2,987	2,793	2,286
CMS Programs												
Total Medicaid (excluding Medicaid SCHIP expansion)	249,048	223,015	202,359	186,226	171,369	159,528	152,160	144,038	133,748	121,611	108,187	93,240
Total Medicaid SCHIP expansion and SCHIP	5,604	4,322	2,955	1,602	346	0	0	0	0	0	0	0
Total CMS Programs (Medicaid, SCHIP and Medicare)	521,757	473,837	430,370	401,342	381,962	369,066	350,507	327,135	300,069	269,947	244,485	214,154
POPULATION	285	283	280	278	275	273	270	268	265	263	260	257
Health Svcs and Supplies	1,496,336	1,370,040	1,261,449	1,181,672	1,112,057	1,055,545	1,005,114	957,643	904,680	856,274	797,125	734,560
Private Funds	819,741	751,032	697,253	654,313	613,430	574,314	543,644	521,136	496,200	484,049	456,044	429,786
Consumer Payments	762,082	696,088	641,913	597,145	558,185	522,186	495,663	476,230	455,476	445,026	419,760	396,032
Out-of-pocket Payments	212,510	200,529	192,564	184,475	175,305	162,065	151,884	146,486	143,790	146,948	145,923	142,133
Pvt Health Insurance	549,572	495,559	449,349	412,671	382,880	360,120	343,779	329,744	311,686	298,078	273,837	253,899
Other Private Funds	57,659	54,944	55,340	57,168	55,245	52,128	47,981	44,906	40,723	39,023	36,284	33,754
Industrial Inplant	4,653	4,443	4,238	3,963	3,776	3,605	3,427	3,259	3,057	2,840	2,627	2,427
Other Private Revenues Including Philan.	53,006	50,500	51,102	53,204	51,469	48,523	44,554	41,647	37,667	36,183	33,657	31,327
Public Funds	676,595	619,008	564,196	527,359	498,627	481,232	461,470	436,506	408,480	372,225	341,081	304,774
Federal Funds	476,463	434,590	393,283	367,364	351,846	344,529	330,080	308,122	285,542	261,344	238,453	210,063
Medicare	267,105	246,500	225,055	213,513	210,247	209,538	198,347	183,097	166,321	148,336	136,298	120,913
Workers' Compensation	732	706	663	601	572	565	561	568	600	600	575	530
Public Assistance	150,477	134,159	119,703	109,056	99,800	94,837	92,127	86,177	81,299	76,762	67,957	56,694

Medicaid (Title XIX)	146,558	131,142	117,644	107,945	99,562	94,837	92,127	86,177	81,299	76,762	67,957	56,694
Medicaid SCHIP Expa	989	883	753	434	111	0	0	0	0	0	0	0
SCHIP (Title XXI)	2,930	2,134	1,306	677	128	0	0	0	0	0	0	0
Non-XIX Federal	0	0	0	0	0	0	0	0	0	0	0	0
Department of Defense	17,238	15,204	13,952	12,878	12,246	12,082	11,952	12,059	11,819	12,053	11,593	11,564
Maternal/Child Health	626	612	608	605	586	581	580	587	594	578	566	517
Veterans' Administration	22,255	21,713	19,096	17,657	16,930	16,334	16,261	15,410	15,121	14,140	13,063	12,241
Vocational Rehabilitation	641	621	594	576	570	563	525	529	521	464	478	452
General Hospital/Medical	0	0	0	0	0	0	0	0	0	0	0	0
Gen Hosp/Med NEC	5,441	5,097	4,372	3,917	3,308	3,035	2,726	2,458	2,391	2,174	1,975	1,772
ADAMHA/SAMHSA	2,972	2,774	2,637	2,420	1,996	1,500	1,783	2,067	1,889	1,714	1,685	1,656
Indian Health Services	1,934	1,905	1,757	1,616	1,560	1,570	1,467	1,520	1,361	1,379	1,349	1,127
O.E.O.	0	0	0	0	0	0	0	0	0	0	0	0
Public Health Activity	7,041	5,298	4,847	4,525	4,030	3,924	3,753	3,650	3,626	3,144	2,914	2,595
State and Local Funds	200,132	184,418	170,912	159,995	146,781	136,702	131,389	128,385	122,938	110,880	102,628	94,712
Temporary Disability	49	50	48	49	54	58	54	52	53	52	70	66
Workers' Compensation	29,281	26,943	24,667	22,180	20,142	19,984	21,345	21,346	21,562	21,025	20,524	18,428
Public Assistance	109,120	98,042	89,595	82,641	76,842	69,858	65,447	63,298	57,900	49,886	45,761	41,733
Medicaid (Title XIX)	102,489	91,873	84,715	78,282	71,808	64,691	60,033	57,861	52,449	44,849	40,230	36,546
Medicaid SCHIP Expa	399	355	293	166	43	0	0	0	0	0	0	0
SCHIP (Title XXI)	1,286	950	603	324	64	0	0	0	0	0	0	0
Non-XIX State/Local	0	0	0	0	0	0	0	0	0	0	0	0
General Assistance	4,945	4,864	3,983	3,869	4,928	5,167	5,414	5,437	5,451	5,037	5,531	5,187
Maternal/Child Health	2,185	2,148	2,068	2,003	1,832	1,764	1,683	1,625	1,568	1,504	1,465	1,430
Vocational Rehabilitation	202	203	192	189	186	183	180	177	173	155	144	132
St/L Hosp + School Hlth	15,177	14,005	13,372	13,730	13,757	13,341	13,515	14,107	15,300	14,185	12,733	13,070
Public Health Activity	44,118	43,027	40,969	39,202	33,967	31,515	29,164	27,781	26,382	24,075	21,931	19,852
CMS Programs												
Total Medicaid (excluding Medicaid expansion)	249,048	223,015	202,359	186,226	171,369	159,528	152,160	144,038	133,748	121,611	108,187	93,240
Total Medicaid SCHIP expansion and SCHIP	5,604	4,322	2,955	1,602	346	0	0	0	0	0	0	0
Total CMS Programs (Medicaid, SCHIP and Medicare)	521,757	473,837	430,370	401,342	381,962	369,066	350,507	327,135	300,069	269,947	244,485	214,154
Personal Health Care	1,340,226	1,231,396	1,135,324	1,064,960	1,009,593	959,228	911,149	865,700	816,469	775,751	728,933	672,030
Private Funds	748,059	691,438	645,532	607,088	571,704	532,668	501,349	479,502	455,354	445,252	424,214	399,777
Consumer Payments	691,843	637,767	591,297	550,916	517,341	481,289	454,087	435,264	415,237	406,813	388,520	366,637
Out-of-pocket Payments	212,510	200,529	192,564	184,475	175,305	162,065	151,884	146,486	143,790	146,948	145,923	142,133

Pvt Health Insurance	479,333	437,238	398,733	366,441	342,036	319,224	302,203	288,778	271,447	259,865	242,597	224,504
Other Private Funds	56,216	53,671	54,235	56,173	54,363	51,378	47,262	44,237	40,117	38,439	35,694	33,140
Industrial Inplant	4,653	4,443	4,238	3,963	3,776	3,605	3,427	3,259	3,057	2,840	2,627	2,427
Other Private Revenues Including Philan.	51,563	49,227	49,997	52,209	50,587	47,773	43,835	40,978	37,061	35,599	33,067	30,713
Public Funds	592,167	539,958	489,792	457,872	437,889	426,560	409,800	386,199	361,115	330,499	304,719	272,253
Federal Funds	450,453	412,128	371,999	347,668	334,681	329,751	316,456	295,381	273,545	250,564	229,177	201,479
Medicare	259,099	239,212	217,466	206,173	203,994	203,554	193,085	178,649	162,066	144,355	132,844	117,638
Workers' Compensation	708	682	642	583	554	547	544	551	582	584	560	516
Public Assistance	140,371	125,054	111,499	101,808	93,409	90,406	87,908	81,941	77,589	73,481	65,376	54,257
Medicaid (Title XIX)	137,042	122,489	109,782	100,867	93,207	90,406	87,908	81,941	77,589	73,481	65,376	54,257
Medicaid SCHIP Expa	872	778	662	384	99							
SCHIP (Title XXI)	2,457	1,787	1,055	558	103							
Non-XIX Federal	0	0	0	0	0	0	0	0	0	0	0	0
Department of Defense	16,651	14,693	13,538	12,507	11,949	11,830	11,745	11,855	11,625	11,883	11,424	11,436
Maternal/Child Health	622	608	605	601	582	577	576	583	590	574	562	514
Veterans' Administration	22,161	21,621	19,015	17,583	16,861	16,266	16,190	15,336	15,042	14,057	13,006	12,187
Vocational Rehabilitation	567	550	526	511	507	501	470	478	470	411	427	406
General Hospital/Medical	0	0	0	0	0	0	0	0	0	0	0	0
Gen Hosp/Med NEC	5,441	5,097	4,372	3,917	3,308	3,035	2,726	2,458	2,391	2,174	1,975	1,772
ADAMHA/SAMHSA	2,904	2,711	2,584	2,374	1,960	1,469	1,748	2,016	1,832	1,671	1,657	1,631
Indian Health Services	1,929	1,899	1,752	1,611	1,556	1,566	1,462	1,516	1,357	1,374	1,345	1,122
O.E.O.												
State and Local Funds	141,713	127,830	117,793	110,204	103,208	96,809	93,344	90,817	87,570	79,934	75,542	70,773
Temporary Disability	49	50	48	49	54	58	54	52	53	52	70	66
Workers' Compensation	22,524	20,621	19,034	17,294	15,742	15,172	16,022	16,177	16,578	16,942	17,701	16,329
Public Assistance	101,768	90,992	83,261	77,116	71,807	66,464	62,054	58,839	54,052	47,248	43,572	39,881
Medicaid (Title XIX)	95,396	85,019	78,532	72,830	66,789	61,297	56,640	53,401	48,601	42,211	38,041	34,694
Medicaid SCHIP Expa	351	311	256	146	38							
SCHIP (Title XXI)	1,076	798	489	270	52							
Non-XIX State/Local	0	0	0	0	0	0	0	0	0	0	0	0
General Assistance	4,945	4,864	3,983	3,869	4,928	5,167	5,414	5,437	5,451	5,037	5,531	5,187
Maternal/Child Health	2,016	1,982	1,908	1,848	1,682	1,612	1,537	1,483	1,431	1,371	1,337	1,309
Vocational Rehabilitation	179	180	170	167	165	163	161	160	156	137	128	118
St/L Hosp + School Hlth	15,177	14,005	13,372	13,730	13,757	13,341	13,515	14,107	15,300	14,185	12,733	13,070
CMS Programs												

Total Medicaid (excluding Medicaid expansion)	232,438	207,508	188,314	173,697	159,996	151,703	144,548	135,342	126,190	115,691	103,418	88,951
Total Medicaid SCHIP expansion and SCHIP	4,756	3,674	2,463	1,358	292							
Total CMS Programs (Medicaid, SCHIP and Medicare)	496,293	450,394	408,243	381,228	364,282	355,257	337,633	313,991	288,256	260,046	236,262	206,589
Hospital Care	486,511	444,316	413,178	393,464	378,535	367,613	355,210	343,580	332,398	319,962	302,267	279,485
Private Funds	200,066	181,672	170,401	160,827	152,318	143,893	138,191	136,935	135,152	136,237	130,534	126,073
Consumer Payments	179,757	162,598	150,222	140,332	132,594	125,882	122,358	122,238	121,925	123,739	118,954	114,954
Out-of-pocket Payments	14,742	13,104	12,675	12,435	11,908	11,112	10,483	10,526	11,044	12,589	12,410	11,972
Pvt Health Insurance	165,015	149,494	137,547	127,897	120,686	114,770	111,875	111,712	110,881	111,150	106,544	102,982
Other Private Funds	20,309	19,074	20,179	20,495	19,724	18,012	15,833	14,697	13,227	12,498	11,580	11,119
Industrial Inplant	0	0	0	0	0	0	0	0	0	0	0	0
Other Private Revenues Including Philan.	20,309	19,074	20,179	20,495	19,724	18,012	15,833	14,697	13,227	12,498	11,580	11,119
Public Funds	286,445	262,644	242,777	232,637	226,217	223,720	217,019	206,646	197,246	183,726	171,733	153,412
Federal Funds	229,936	211,593	194,154	185,967	181,527	182,182	176,370	166,409	156,735	146,908	136,699	119,425
Medicare	149,241	137,188	126,923	122,589	121,580	122,530	115,988	107,211	98,833	90,123	84,125	73,825
Workers' Compensation	358	348	327	298	287	287	290	295	315	318	306	283
Public Assistance	50,999	46,078	41,569	39,365	36,390	36,335	37,031	35,926	35,160	34,334	31,395	25,229
Medicaid (Title XIX)	49,808	45,158	40,998	39,089	36,299	36,335	37,031	35,926	35,160	34,334	31,395	25,229
Medicaid SCHIP Expa	289	264	254	150	40	0	0	0	0	0	0	0
SCHIP (Title XXI)	902	656	317	125	51	0	0	0	0	0	0	0
Non-XIX Federal		0	0	0	0	0	0	0	0	0	0	0
Department of Defense	10,260	9,386	8,990	8,692	8,896	8,915	8,923	9,342	9,155	9,569	9,098	9,110
Maternal/Child Health	40	41	42	40	43	46	49	53	57	59	61	57
Veterans' Administration	16,592	16,259	14,409	13,329	12,837	12,609	12,694	12,198	11,925	11,239	10,465	9,814
Vocational Rehabilitation	299	285	264	241	243	239	231	235	229	180	193	186
General Hospital/Medi	0	0	0	0	0	0	0	0	0	0	0	0
Gen Hosp/Med NEC	1,080	960	657	516	384	344	343	307	309	320	303	280
ADAMHA/SAMHSA	0	0	0	0	0	0	0	0	0	0	0	9
Indian Health Services	1,067	1,050	973	898	867	877	821	842	752	765	752	631
O.E.O.		0	0	0	0	0	0	0	0	0	0	0
State and Local Funds	56,509	51,051	48,622	46,670	44,691	41,539	40,649	40,236	40,511	36,818	35,034	33,987
Temporary Disability	19	19	19	19	21	23	22	21	22	22	29	28
Workers' Compensation	9,625	8,809	8,163	7,483	6,892	6,770	7,238	7,353	7,620	7,826	8,203	7,584
Public Assistance	35,683	32,087	30,618	28,904	27,315	24,611	22,926	21,628	20,280	17,214	16,276	15,354

Medicaid (Title XIX)	33,325	29,732	28,877	27,162	24,678	21,793	19,884	18,550	16,983	14,118	12,683	11,988
Medicaid SCHIP Expa	121	107	101	59	16	0	0	0	0	0	0	0
SCHIP (Title XXI)	414	303	149	62	26	0	0	0	0	0	0	0
Non-XIX State/Local	0	0	0	0	0	0	0	0	0	0	0	0
General Assistance	1,824	1,945	1,492	1,621	2,595	2,818	3,042	3,079	3,298	3,096	3,593	3,366
Maternal/Child Health	95	100	103	103	105	113	117	122	126	129	133	135
Vocational Rehabilitation	94	93	86	81	79	78	79	78	76	60	58	54
St/L Hosp + School Hlth	10,993	9,941	9,634	10,081	10,278	9,944	10,265	11,033	12,387	11,567	10,334	10,831
CMS Programs												
Total Medicaid (excluding Medicaid expansion)	83,132	74,891	69,875	66,251	60,977	58,128	56,915	54,476	52,143	48,452	44,079	37,217
Total Medicaid SCHIP expansion and SCHIP	1,726	1,329	821	396	132	0	0	0	0	0	0	0
Total CMS Programs (Medicaid, SCHIP and Medicare)	234,099	213,408	197,618	189,236	182,690	180,658	172,904	161,687	150,975	138,575	128,204	111,042
Physician and Clinical Services	339,543	315,137	290,304	270,883	256,830	240,970	229,393	220,534	210,483	201,239	189,721	175,003
Private Funds	224,729	208,733	194,287	183,170	176,059	165,097	156,752	150,782	145,480	140,910	132,485	121,869
Consumer Payments	201,136	186,496	172,986	160,712	154,401	145,008	137,930	133,209	129,306	126,015	118,704	109,459
Out-of-pocket Payments	34,258	33,121	32,113	31,755	30,902	28,749	26,949	26,224	27,874	29,745	30,681	30,978
Pvt Health Insurance	166,878	153,375	140,873	128,957	123,499	116,259	110,981	106,985	101,433	96,270	88,023	78,480
Other Private Funds	23,594	22,237	21,301	22,458	21,659	20,089	18,822	17,574	16,174	14,895	13,781	12,411
Industrial Inplant		0	0	0	0	0	0	0	0	0	0	0
Other Private Revenues Including Philan.	23,594	22,237	21,301	22,458	21,659	20,089	18,822	17,574	16,174	14,895	13,781	12,411
Public Funds	114,814	106,405	96,018	87,713	80,771	75,872	72,641	69,752	65,003	60,329	57,236	53,134
Federal Funds	94,742	88,128	79,659	72,744	66,770	62,350	59,166	56,416	52,100	47,821	44,942	42,167
Medicare	68,828	65,070	59,352	54,502	50,513	47,117	44,183	41,873	38,392	34,724	33,038	31,777
Workers' Compensation	150	146	137	125	118	115	113	115	121	121	117	108
Public Assistance	15,392	13,527	11,784	10,679	9,915	9,567	9,268	8,678	8,114	7,641	6,613	5,290
Medicaid (Title XIX)	14,452	12,790	11,272	10,345	9,871	9,567	9,268	8,678	8,114	7,641	6,613	5,290
Medicaid SCHIP Expa	183	163	130	75	19	0	0	0	0	0	0	0
SCHIP (Title XXI)	757	574	382	259	25	0	0	0	0	0	0	0
Non-XIX Federal												
Department of Defense	3,605	3,048	2,689	2,219	1,667	1,626	1,589	1,571	1,579	1,693	1,631	1,666
Maternal/Child Health	93	93	93	99	97	97	96	99	101	99	98	91
Veterans' Administration	1,420	1,322	1,085	972	902	804	738	623	575	533	478	452
Vocational Rehabilitation	216	215	214	212	218	218	196	199	198	193	195	182

General Hospital/Medical	0	0	0	0	0	0	0	0	0	0	0	0
Gen Hosp/Med NEC	1,584	1,459	1,223	1,101	938	899	832	826	815	763	741	668
ADAMHA/SAMHSA	2,904	2,711	2,584	2,374	1,960	1,469	1,748	2,016	1,832	1,671	1,657	1,622
Indian Health Services	550	539	499	462	442	439	403	417	373	381	374	311
O.E.O.		0	0	0	0	0	0	0	0	0	0	0
State and Local Funds	20,072	18,277	16,358	14,970	14,000	13,522	13,475	13,336	12,904	12,508	12,294	10,967
Temporary Disability	24	25	24	24	27	28	27	25	26	25	34	32
Workers' Compensation	8,889	8,205	7,585	6,882	6,255	5,947	6,250	6,323	6,464	6,595	6,898	6,363
Public Assistance	10,934	9,819	8,524	7,839	7,506	7,342	7,005	6,797	6,226	5,705	5,184	4,399
Medicaid (Title XIX)	10,028	8,989	7,818	7,220	6,864	6,706	6,381	6,164	5,613	5,049	4,539	3,823
Medicaid SCHIP Expa	70	63	50	28	7							
SCHIP (Title XXI)	330	257	180	127	13							
Non-XIX State/Local	0	0	0	0	0	0	0	0	0	0	0	0
General Assistance	506	510	476	464	622	636	625	633	613	656	645	576
Maternal/Child Health	157	158	156	153	142	135	126	124	122	119	120	120
Vocational Rehabilitation	68	70	69	71	71	70	67	67	66	64	59	53
St/L Hosp + School Hlth	0	0	0	0	0	0	0	0	0	0	0	0
CMS Programs												
Total Medicaid (excluding Medicaid expansion)	24,480	21,779	19,090	17,566	16,734	16,273	15,649	14,842	13,728	12,690	11,152	9,113
Total Medicaid SCHIP expansion and SCHIP	1,340	1,056	741	489	64							
Total CMS Programs (Medicaid, SCHIP & Medicare)	94,648	87,905	79,183	72,556	67,311	63,390	59,831	56,715	52,119	47,415	44,190	40,890
Dental Services	70,319	65,614	60,726	56,389	53,156	50,168	46,818	44,486	41,432	38,878	37,013	33,279
Private Funds	65,770	61,717	57,657	53,778	50,744	47,905	44,693	42,437	39,470	37,005	35,631	32,172
Consumer Payments	65,702	61,580	57,488	53,638	50,610	47,774	44,573	42,355	39,390	36,931	35,563	32,108
Out-of-pocket Payments	30,869	28,400	26,992	24,872	23,650	22,157	20,157	19,392	18,356	17,515	17,164	15,772
Pvt Health Insurance	34,833	33,181	30,496	28,766	26,960	25,618	24,415	22,963	21,034	19,416	18,399	16,335
Other Private Funds	68	137	169	140	134	130	120	82	80	74	69	65
Industrial Inplant												
Other Private Revenues Including Philan.	68	137	169	140	134	130	120	82	80	74	69	65
Public Funds	4,549	3,898	3,069	2,611	2,412	2,263	2,125	2,049	1,962	1,873	1,382	1,107
Federal Funds	2,715	2,314	1,838	1,550	1,444	1,314	1,223	1,151	1,094	1,070	793	623
Medicare	94	97	104	90	154	88	53	37	24	18	4	2
Workers' Compensation												

Public Assistance	2,479	2,078	1,603	1,344	1,180	1,115	1,082	1,001	988	949	878	527
Medicaid (Title XIX)	2,075	1,767	1,419	1,243	1,164	1,115	1,082	1,001	988	949	878	527
Medicaid SCHIP Expa	74	67	55	30	9							
SCHIP (Title XXI)	330	243	130	71	7							
Non-XIX Federal												
Department of Defense	24	22	22	20	17	17	18	20	20	22	23	24
Maternal/Child Health	15	15	15	15	14	14	13	13	13	12	13	11
Veterans' Administration	14	14	13	11	11	12	12	12	11	9	17	10
Vocational Rehabilitation	0	0	0	0	0	0	0	0	0	0	0	0
General Hospital/Medical	0	0	0	0	0	0	0	0	0	0	0	0
Gen Hosp/Med NEC	0	0	0	0	0	0	0	0	0	0	0	0
ADAMHA/SAMHSA	0	0	0	0	0	0	0	0	0	0	0	0
Indian Health Services	89	89	81	71	68	68	64	68	60	59	59	48
O.E.O.	0	0	0	0	0	0	0	0	0	0	0	0
State and Local Funds	1,835	1,583	1,232	1,061	968	949	902	898	867	803	589	484
Temporary Disability	0	0	0	0	0	0	0	0	0	0	0	0
Workers' Compensation	0	0	0	0	0	0	0	0	0	0	0	0
Public Assistance	1,825	1,572	1,220	1,049	958	939	894	891	861	798	583	478
Medicaid (Title XIX)	1,616	1,398	1,101	959	891	869	829	815	782	727	519	419
Medicaid SCHIP Expa	29	28	21	12	3	0	0	0	0	0	0	0
SCHIP (Title XXI)	138	103	58	33	3	0	0	0	0	0	0	0
Non-XIX State/Local	0	0	0	0	0	0	0	0	0	0	0	0
General Assistance	42	45	41	46	61	70	66	76	79	70	64	60
Maternal/Child Health	10	11	12	11	10	10	8	7	7	5	6	5
Vocational Rehabilitation	0	0	0	0	0	0	0	0	0	0	0	0
SVL Hosp + School Hlth	0	0	0	0	0	0	0	0	0	0	0	0
CMS Programs												
Total Medicaid (excluding Medicaid expansion)	3,690	3,165	2,519	2,202	2,055	1,984	1,891	1,815	1,747	1,676	1,196	945
Total Medicaid SCHIP expansion and SCHIP	571	440	263	146	23	0	0	0	0	0	0	0
Total CMS Programs (Medicaid, SCHIP and Medicare)	4,356	3,702	2,886	2,437	2,232	2,072	1,944	1,852	1,771	1,694	1,201	948
Other Professional Services	45,852	42,633	38,791	36,652	35,496	33,378	30,877	28,555	25,669	24,478	22,185	19,694
Private Funds	33,208	31,698	29,270	28,159	27,407	25,496	23,127	21,192	18,836	18,059	16,306	14,435
Consumer Payments	30,206	28,769	26,377	25,161	24,260	22,502	20,321	18,573	16,426	15,840	14,252	12,586
Out-of-pocket Payments	13,046	12,381	11,570	11,086	10,591	9,494	8,286	7,770	7,051	6,976	6,441	5,836
Pvt Health Insurance	17,160	16,388	14,808	14,075	13,669	13,008	12,035	10,803	9,375	8,863	7,811	6,750

Other Private Funds	3,003	2,930	2,893	2,999	3,146	2,994	2,805	2,819	2,411			
Industrial Inplant		0	0	0	0	0	0	0	0			
Other Private Revenues Including Philan.	3,003	2,930	2,893	2,999	3,146	2,994	2,805	2,819	2,411			
										2,220	2,054	1,850
Public Funds	12,644	10,935	9,521	8,493	8,089	7,882	7,751	7,363	6,833	0	0	0
Federal Funds	8,211	7,046	5,995	5,264	5,156	5,032	4,869	4,571	4,117			
Medicare	6,444	5,655	4,783	4,158	4,125	4,001	3,896	3,720	3,341	2,220	2,054	1,850
Workers' Compensation	169	162	152	138	130	128	126	126	131			
Public Assistance	1,434	1,069	901	817	756	761	706	583	501	6,418	5,879	5,259
Medicaid (Title XIX)	1,344	1,009	860	799	753	761	706	583	501	3,724	3,217	2,801
Medicaid SCHIP Expa	34	21	19	8	2	0	0	0	0	2,953	2,617	2,261
SCHIP (Title XXI)	56	39	23	10	1	0	0	0	0	130	123	112
Non-XIX Federal	0	0	0	0	0	0	0	0	0	501	340	303
Department of Defense	0	0	0	0	0	0	0	0	0	501	340	303
Maternal/Child Health	164	160	159	151	146	142	142	143	14	0	0	0
Veterans' Administration	0	0	0	0	0	0	0	0	0	0	0	0
Vocational Rehabilitation	0	0	0	0	0	0	0	0	0	0	0	0
General Hospital/Medical	0	0	0	0	0	0	0	0	0	0	0	0
Gen Hosp/Med NEC	0	0	0	0	0	0	0	0	0	140	137	124
ADAMHA/SAMHSA	0	0	0	0	0	0	0	0	0	0	0	0
Indian Health Services	0	0	0	0	0	0	0	0	0	0	0	0
O.E.O.	0	0	0	0	0	0	0	0	0	0	0	0
State and Local Funds	4,433	3,889	3,526	3,228	2,933	2,850	2,882	2,791	2,71	0	0	0
Temporary Disability	3	3	3	3	3	4	3	3		0	0	0
Workers' Compensation	2,964	2,699	2,490	2,356	2,048	1,965	2,049	2,037	2,04	0	0	0
Public Assistance	1,114	840	699	644	585	597	559	492	42	0	0	0
Medicaid (Title XIX)	1,012	764	637	586	548	556	513	437	36	2,695	2,663	2,458
Medicaid SCHIP Expa	15	9	7	3	1	0	0	0	0	3	4	3
SCHIP (Title XXI)	22	16	10	5	0	0	0	0	0	2,070	2,126	1,942
Non-XIX State/Local	0	0	0	0	0	0	0	0	0	385	302	288
General Assistance	64	51	45	50	36	41	46	54	5	333	254	246
Maternal/Child Health	352	347	334	325	297	285	271	260	24	0	0	0
Vocational Rehabilitation	0	0	0	0	0	0	0	0	0	0	0	0
St/L Hosp + School Hlth	0	0	0	0	0	0	0	0	0	0	0	0
CMS Programs										51	48	42
Total Medicaid (excluding Medicaid expansion)	2,357	1,772	1,497	1,386	1,301	1,317	1,219	1,020	86	237	232	225
										0	0	0
										0	0	0
										834	594	549

Total Medicaid SCHIP expansion and SCHIP	127	85	59	26	4	0	0	0	0	0	0	0
Total CMS Programs (Medicaid, SCHIP and Medicare)	8,927	7,512	6,338	5,569	5,429	5,318	5,114	4,740	4,203	3,787	3,211	2,810
Home Health Care	36,129	33,699	31,728	32,318	33,575	34,544	33,602	30,529	26,066	21,879	18,170	14,879
Private Funds	14,278	14,140	15,267	16,461	16,307	14,796	12,944	11,191	9,528	8,501	7,398	6,647
Consumer Payments	13,226	13,011	13,953	14,842	14,925	13,441	11,663	9,994	8,428	7,440	6,400	5,678
Out-of-pocket Payments	6,493	6,104	6,237	6,673	6,623	5,946	5,147	4,403	3,709	3,275	2,819	2,507
Pvt Health Insurance	6,734	6,907	7,715	8,169	8,301	7,495	6,516	5,591	4,718	4,165	3,580	3,171
Other Private Funds	1,051	1,129	1,315	1,619	1,382	1,355	1,281	1,197	1,101	1,061	998	969
Industrial Inplant												
Other Private Revenues Including Philan.	1,051	1,129	1,315	1,619	1,382	1,355	1,281	1,197	1,101	1,061	998	969
Public Funds	21,852	19,559	16,461	15,857	17,268	19,748	20,658	19,338	16,537	13,378	10,772	8,233
Federal Funds	16,184	14,362	12,071	11,658	13,193	15,850	16,962	15,801	13,313	10,489	8,179	5,973
Medicare	11,415	10,077	8,567	8,513	10,164	13,098	14,431	13,478	11,231	8,541	6,541	4,626
Workers' Compensation	0	0	0	0	0	0	0	0	0	0	0	0
Public Assistance	4,610	4,139	3,394	3,051	2,943	2,673	2,465	2,271	2,034	1,904	1,598	1,311
Medicaid (Title XIX)	4,603	4,134	3,390	3,049	2,943	2,673	2,465	2,271	2,034	1,904	1,598	1,311
Medicaid SCHIP Expa	3	2	3	2	0	0	0	0	0	0	0	0
SCHIP (Title XXI)	4	3	1	0	0	0	0	0	0	0	0	0
Non-XIX Federal	0	0	0	0	0	0	0	0	0	0	0	0
Department of Defense	0	0	0	0	0	0	0	0	0	0	0	0
Maternal/Child Health	0	0	0	0	0	0	0	0	0	0	0	0
Veterans' Administration	160	146	110	95	86	78	66	52	47	44	39	35
Vocational Rehabilitation	0	0	0	0	0	0	0	0	0	0	0	0
General Hospital/Medical	0	0	0	0	0	0	0	0	0	0	0	0
Gen Hosp/Med NEC	0	0	0	0	0	0	0	0	0	0	0	0
ADAMHA/SAMHSA	0	0	0	0	0	0	0	0	0	0	0	0
Indian Health Services	0	0	0	0	0	0	0	0	0	0	0	0
O.E.O.	0	0	0	0	0	0	0	0	0	0	0	0
State and Local Funds	5,667	5,197	4,390	4,198	4,075	3,898	3,696	3,537	3,225	2,889	2,594	2,260
Temporary Disability	0	0	0	0	0	0	0	0	0	0	0	0
Workers' Compensation	0	0	0	0	0	0	0	0	0	0	0	0
Public Assistance	3,868	3,519	2,873	2,620	2,525	2,301	2,120	2,040	1,819	1,630	1,438	1,226
Medicaid (Title XIX)	3,836	3,485	2,845	2,559	2,450	2,220	2,035	1,965	1,753	1,584	1,395	1,191

Medicaid SCHIP Expa	1	1	1	1	0	0	0	0	0	0	0	0
SCHIP (Title XXI)	2	1	1	0	0	0	0	0	0	0	0	0
Non-XIX State/Local	0	0	0	0	0	0	0	0	0	0	0	0
General Assistance	29	31	26	60	75	81	85	76	66	46	42	35
Maternal/Child Health	0	0	0	0	0	0	0	0	0	0	0	0
Vocational Rehabilitation	0	0	0	0	0	0	0	0	0	0	0	0
St/L Hosp + School Hlth	1,800	1,679	1,517	1,578	1,550	1,597	1,576	1,496	1,406	1,259	1,156	1,034
CMS Programs												
Total Medicaid (excluding Medicaid expansion)	8,439	7,619	6,235	5,608	5,393	4,893	4,499	4,236	3,788	3,488	2,993	2,502
Total Medicaid SCHIP expansion and SCHIP	10	7	6	3	1	0	0	0	0	0	0	0
Total CMS Programs (Medicaid, SCHIP and Medicare)	19,864	17,703	14,807	14,123	15,557	17,992	18,931	17,714	15,019	12,029	9,535	7,128
Other Non-Durable Medical Products	31,733	31,030	30,794	30,332	28,596	27,880	27,097	25,561	24,256	23,424	23,213	23,256
Private Funds	30,139	29,560	29,476	29,142	27,407	26,710	26,003	24,475	23,337	22,575	22,432	22,567
Consumer Payments	30,139	29,560	29,476	29,142	27,407	26,710	26,003	24,475	23,337	22,575	22,432	22,567
Out-of-pocket Payments	30,139	29,560	29,476	29,142	27,407	26,710	26,003	24,475	23,337	22,575	22,432	22,567
Pvt Health Insurance			0	0	0	0	0	0	0	0	0	0
Public Funds	1,594	1,470	1,317	1,189	1,188	1,170	1,094	1,086	920	849	781	689
Medicare	1,594	1,470	1,317	1,189	1,188	1,170	1,094	1,086	920	849	781	689
Prescription Drugs	162,413	140,815	121,540	104,421	87,271	75,747	67,160	60,779	54,636	51,250	48,224	44,892
Private Funds	126,173	109,323	94,879	82,220	68,832	60,024	53,350	48,534	43,839	41,636	39,525	37,136
Consumer Payments	126,173	109,323	94,879	82,220	68,832	60,024	53,350	48,534	43,839	41,636	39,525	37,136
Out-of-pocket Payments	48,605	42,503	38,324	34,361	30,485	27,874	26,497	25,970	26,315	27,031	26,377	25,241
Pvt Health Insurance	77,569	66,820	56,555	47,858	38,347	32,150	26,853	22,564	17,524	14,606	13,148	11,895
Other Private Funds	0	0	0	0	0	0	0	0	0	0	0	0
Industrial Inplant												
Other Private Revenues including philan.	0	0	0	0	0	0	0	0	0	0	0	0
Public Funds	36,239	31,492	26,661	22,201	18,439	15,723	13,810	12,245	10,797	9,614	8,700	7,756
Federal Funds	20,866	18,042	15,306	12,755	10,504	8,952	7,763	6,632	5,760	5,127	4,464	3,836
Medicare	2,634	2,461	2,302	2,127	1,771	1,387	1,090	776	521	384	305	250
Workers' Compensation	28	25	22	19	16	14	13	12	12	12	11	11
Public Assistance	16,865	14,577	12,203	10,009	8,307	7,170	6,348	5,579	5,002	4,542	3,990	3,437

Medicaid (Title XIX)	16,465	14,278	11,977	9,894	8,283	7,170	6,348	5,579	5,002	4,542	3,990	3,437
Medicaid SCHIP Expa	144	112	90	49	13	0	0	0	0	0	0	0
SCHIP (Title XXI)	256	187	135	67	12	0	0	0	0	0	0	0
Non-XIX Federal	0	0	0	0	0	0	0	0	0	0	0	0
Department of Defense	1,214	880	704	526	348	324	261	214	178	146	114	99
Maternal/Child Health	43	39	36	40	35	33	30	28	27	25	25	23
Veterans' Administration	72	49	30	25	18	14	13	13	11	10	10	10
Vocational Rehabilitation	0	0	0	0	0	0	0	0	0	0	0	0
General Hospital/Medical	0	0	0	0	0	0	0	0	0	0	0	0
Gen Hosp/Med NEC	0	0	0	0	0	0	0	0	0	0	0	0
ADAMHA/SAMHSA	0	0	0	0	0	0	0	0	0	0	0	0
Indian Health Services	10	10	9	9	9	9	9	10	9	9	9	7
O.E.O.	0	0	0	0	0	0	0	0	0	0	0	0
State and Local Funds	15,373	13,450	11,355	9,446	7,935	6,771	6,047	5,613	5,038	4,487	4,235	3,920
Temporary Disability	2	2	2	2	2	2	1	1	1	1	2	2
Workers' Compensation	947	814	707	589	470	414	405	386	372	372	388	361
Public Assistance	14,288	12,511	10,539	8,762	7,393	6,302	5,598	5,190	4,635	4,088	3,820	3,531
Medicaid (Title XIX)	11,943	10,393	8,791	7,352	6,132	5,197	4,551	4,163	3,650	3,184	2,894	2,607
Medicaid SCHIP Expa	56	43	34	18	5	0	0	0	0	0	0	0
SCHIP (Title XXI)	105	80	61	31	6	0	0	0	0	0	0	0
Non-XIX State/Local	0	0	0	0	0	0	0	0	0	0	0	0
General Assistance	2,184	1,995	1,653	1,361	1,251	1,105	1,047	1,027	985	904	927	924
Maternal/Child Health	135	123	107	93	70	53	43	36	30	26	25	26
Vocational Rehabilitation	0	0	0	0	0	0	0	0	0	0	0	0
St/L Hosp + School Hlth	0	0	0	0	0	0	0	0	0	0	0	0
CMS Programs												
Total Medicaid (excluding Medicaid expansion)	28,408	24,671	20,769	17,245	14,414	12,367	10,899	9,742	8,652	7,726	6,883	6,043
Total Medicaid SCHIP expansion and SCHIP	561	423	320	165	35	0	0	0	0	0	0	0
Total CMS Programs (Medicaid, SCHIP and Medicare)	31,603	27,555	23,390	19,537	16,221	13,754	11,989	10,518	9,173	8,110	7,188	6,294
Durable Medical Equipment	18,754	18,162	17,750	17,231	16,851	16,157	15,284	14,185	13,322	12,797	12,229	11,397
Private Funds	11,929	12,142	12,398	12,225	12,133	11,340	10,965	10,200	9,855	9,618	9,311	8,783
Consumer Payments	11,929	12,142	12,398	12,225	12,133	11,340	10,965	10,200	9,855	9,618	9,311	8,783
Out-of-pocket Payments	8,471	8,684	8,971	8,993	8,909	8,430	8,123	7,658	7,643	7,649	7,592	7,149
Pvt Health Insurance	3,459	3,458	3,427	3,232	3,224	2,910	2,842	2,541	2,212	1,969	1,719	1,634
Other Private Funds	0	0	0	0	0	0	0	0	0	0	0	0

Industrial Inplant	0	0	0	0	0	0	0	0	0	0	0	0
Other Private Revenues Including Philan.	0	0	0	0	0	0	0	0	0	0	0	0
Public Funds	6,824	6,020	5,351	5,006	4,718	4,817	4,320	3,985	3,468	3,179	2,918	2,614
Federal Funds	6,631	5,843	5,178	4,848	4,583	4,684	4,184	3,851	3,333	3,047	2,779	2,473
Medicare	5,924	5,188	4,626	4,346	4,138	4,295	3,846	3,527	3,032	2,788	2,547	2,255
Workers' Compensation	3	3	3	3	3	3	3	2	3	3	2	2
Public Assistance	60	40	33	17	2	0	0	0	0	0	0	0
Medicaid (Title XIX)	0	0	0	0	0	0	0	0	0	0	0	0
Medicaid SCHIP Expa	10	8	12	6	1	0	0	0	0	0	0	0
SCHIP (Title XXI)	50	32	21	11	1	0	0	0	0	0	0	0
Non-XIX Federal	0	0	0	0	0	0	0	0	0	0	0	0
Department of Defense	0	0	0	0	0	0	0	0	0	0	0	0
Maternal/Child Health	22	21	22	22	21	21	21	21	22	21	21	19
Veterans' Administration	567	536	442	398	368	315	267	252	229	194	165	156
Vocational Rehabilitation	52	50	48	59	47	46	43	44	43	38	39	37
General Hospital/Medical	0	0	0	0	0	0	0	0	0	0	0	0
Gen Hosp/Med NEC	0	0	0	0	0	0	0	0	0	0	0	0
ADAMHA/SAMHSA	0	0	0	0	0	0	0	0	0	0	0	0
Indian Health Services	5	5	4	4	4	4	4	4	4	4	4	3
O.E.O.	0	0	0	0	0	0	0	0	0	0	0	0
State and Local Funds	193	177	173	158	135	132	136	133	135	132	140	141
Temporary Disability	1	1	1	1	1	1	1	1	1	1	1	1
Workers' Compensation	99	92	90	85	77	77	80	78	79	81	85	80
Public Assistance	39	29	29	21	7	6	7	9	12	10	13	22
Medicaid (Title XIX)	0	0	0	0	0	0	0	0	0	0	0	0
Medicaid SCHIP Expa	4	3	5	3	0	0	0	0	0	0	0	0
SCHIP (Title XXI)	21	13	10	6	1	0	0	0	0	0	0	0
Non-XIX State/Local	0	0	0	0	0	0	0	0	0	0	0	0
General Assistance	14	13	14	12	6	6	7	9	12	10	13	22
Maternal/Child Health	38	38	37	37	35	33	32	31	29	28	28	28
Vocational Rehabilitation	16	17	16	15	15	15	15	15	14	13	12	11
St/L Hosp + School Hlth	0	0	0	0	0	0	0	0	0	0	0	0
CMS Programs												
Total Medicaid (excluding Medicaid expansion)	0	0	0	0	0	0	0	0	0	0	0	0
Total Medicaid SCHIP expansion and SCHIP	85	56	48	26	3	0	0	0	0	0	0	0

Total CMS Programs (Medicaid, SCHIP and Medicare)	6,008	5,244	4,674	4,372	4,141	4,295	3,846	3,527	3,032	2,788	2,547	2,255
Nursing Home Care	103,167	99,116	93,790	89,572	89,103	85,063	79,911	74,574	68,325	65,713	62,304	58,314
Private Funds	37,113	38,010	37,659	37,143	36,722	33,801	31,899	30,496	26,800	27,869	27,965	27,667
Consumer Payments	33,574	34,289	33,518	32,644	32,180	28,608	26,926	25,686	22,732	23,019	23,380	23,367
Out-of-pocket Payments	25,888	26,674	26,206	25,156	24,829	21,594	20,239	20,067	18,461	19,593	20,008	20,111
Pvt Health Insurance	7,687	7,615	7,312	7,488	7,351	7,014	6,687	5,619	4,271	3,426	3,372	3,256
Other Private Funds	3,538	3,720	4,141	4,499	4,542	5,193	4,974	4,810	4,068	4,850	4,585	4,300
Industrial Inplant												
Other Private Revenues Including Philan.	3,538	3,720	4,141	4,499	4,542	5,193	4,974	4,810	4,068	4,850	4,585	4,300
Public Funds	66,054	61,106	56,131	52,429	52,381	51,262	48,011	44,078	41,525	37,844	34,339	30,648
Federal Funds	45,515	42,211	37,668	34,545	35,133	34,290	31,876	28,530	26,657	24,032	21,199	18,381
Medicare	12,925	12,005	9,494	8,659	10,361	9,867	8,505	6,942	5,773	3,976	2,885	1,954
Workers' Compensation												
Public Assistance	30,545	28,130	26,296	24,100	23,023	22,723	21,709	19,994	19,343	18,646	17,071	15,272
Medicaid (Title XIX)	30,541	28,126	26,289	24,093	23,022	22,723	21,709	19,994	19,343	18,646	17,071	15,272
Medicaid SCHIP Expa	3	3	7	7	1	0	0	0	0	0	0	0
SCHIP (Title XXI)	1	1	0	0	0	0	0	0	0	0	0	0
Non-XIX Federal	0	0	0	0	0	0	0	0	0	0	0	0
Department of Defense	0	0	0	0	0	0	0	0	0	0	0	0
Maternal/Child Health	0	0	0	0	0	0	0	0	0	0	0	0
Veterans' Administration	2,045	2,076	1,878	1,786	1,749	1,700	1,661	1,594	1,541	1,410	1,243	1,155
Vocational Rehabilitation	0	0	0	0	0	0	0	0	0	0	0	0
General Hospital/Medical	0	0	0	0	0	0	0	0	0	0	0	0
Gen Hosp/Med NEC	0	0	0	0	0	0	0	0	0	0	0	0
ADAMHA/SAMHSA	0	0	0	0	0	0	0	0	0	0	0	0
Indian Health Services	0	0	0	0	0	0	0	0	0	0	0	0
O.E.O.	0	0	0	0	0	0	0	0	0	0	0	0
State and Local Funds	20,539	18,895	18,463	17,884	17,248	16,973	16,136	15,548	14,868	13,812	13,140	12,267
Temporary Disability	0	0	0	0	0	0	0	0	0	0	0	0
Workers' Compensation	0	0	0	0	0	0	0	0	0	0	0	0
Public Assistance	20,539	18,895	18,463	17,884	17,248	16,973	16,136	15,548	14,868	13,812	13,140	12,267
Medicaid (Title XIX)	20,354	18,723	18,294	17,721	17,090	16,845	16,015	15,440	14,746	13,730	13,071	12,206
Medicaid SCHIP Expa	1	1	2	2	0	0	0	0	0	0	0	0

SCHIP (Title XXI)	0	0	0	0	0	0	0	0	0	0	0	0
Non-XIX Federal	0	0	0	0	0	0	0	0	0	0	0	0
General Assistance	184	170	167	161	157	128	121	108	122	82	69	61
Maternal/Child Health	0	0	0	0	0	0	0	0	0	0	0	0
Vocational Rehabilitation	0	0	0	0	0	0	0	0	0	0	0	0
SVL Hosp + School Hlth	0	0	0	0	0	0	0	0	0	0	0	0
CMS Programs												
Total Medicaid (excluding Medicaid expansion)	50,895	46,849	44,583	41,814	40,112	39,568	37,725	35,434	34,089	32,376	30,142	27,478
Total Medicaid SCHIP expansion and SCHIP	5	6	10	9	2	0	0	0	0	0	0	0
Total CMS Programs (Medicaid, SCHIP and Medicare)	63,825	58,860	54,086	50,482	50,475	49,434	46,229	42,376	39,862	36,352	33,027	29,432
Other Per't Hlth Care	45,803	40,874	36,724	33,698	30,181	27,708	25,798	22,918	19,881	16,130	13,605	11,829
Private Funds	4,653	4,443	4,238	3,963	3,776	3,605	3,427	3,259	3,057	2,840	2,627	2,427
Consumer Payments	0	0	0	0	0	0	0	0	0	0	0	0
Out-of-pocket Payments	0	0	0	0	0	0	0	0	0	0	0	0
Pvt Health Insurance	0	0	0	0	0	0	0	0	0	0	0	0
Other Private Funds	4,653	4,443	4,238	3,963	3,776	3,605	3,427	3,259	3,057	2,840	2,627	2,427
Industrial Inplant	4,653	4,443	4,238	3,963	3,776	3,605	3,427	3,259	3,057	2,840	2,627	2,427
Other Private Revenues Including Philan.	0	0	0	0	0	0	0	0	0	0	0	0
Public Funds	41,151	36,431	32,486	29,735	26,404	24,103	22,371	19,658	16,825	13,290	10,978	9,403
Federal Funds	24,058	21,119	18,811	17,146	15,182	13,928	12,948	10,934	9,517	7,498	6,124	5,113
Medicare	0	0	0	0	0	0	0	0	0	0	0	0
Workers' Compensation	0	0	0	0	0	0	0	0	0	0	0	0
Public Assistance	17,987	15,418	13,717	12,426	10,893	10,062	9,318	7,909	6,466	4,983	3,691	2,888
Medicaid (Title XIX)	17,754	15,227	13,578	12,364	10,873	10,062	9,318	7,909	6,466	4,983	3,691	2,888
Medicaid SCHIP Expa	132	137	92	57	15	0	0	0	0	0	0	0
SCHIP (Title XXI)	101	54	47	14	6	0	0	0	0	0	0	0
Non-XIX Federal	0	0	0	0	0	0	0	0	0	0	0	0
Department of Defense	1,848	1,397	1,133	1,081	1,022	947	984	707	894	483	557	537
Maternal/Child Health	246	240	236	234	226	224	224	225	221	217	208	198
Veterans' Administration	1,291	1,220	1,048	969	889	733	739	592	702	619	589	555
Vocational Rehabilitation	0	0	0	0	0	0	0	0	0	0	0	0
General Hospital/Medical												
Gen Hosp/Med NEC	2,777	2,679	2,192	2,300	1,986	1,792	1,550	1,325	1,267	1,090	931	824

ADAMHA/SAMHSA	0	0	0	0	0	0	0
Indian Health Services	208	206	184	168	166	169	163
O.E.O.	0	0	0	0	0	0	0
State and Local Funds	17,092	15,311	13,874	12,588	11,223	10,175	9,422
Temporary Disability	0	0	0	0	0	0	0
Workers' Compensation	0	0	0	0	0	0	0
Public Assistance	13,478	11,721	10,295	9,393	8,270	7,392	6,808
Medicaid (Title XIX)	13,283	11,536	10,168	9,272	8,137	7,111	6,432
Medicaid SCHIP Expa	53	58	35	21	5	0	0
SCHIP (Title XXI)	44	24	22	7	3	0	0
Non-XIX State/Local	0	0	0	0	0	0	0
General Assistance	98	103	69	94	125	281	376
Maternal/Child Health	1,229	1,206	1,158	1,125	1,023	983	940
Vocational Rehabilitation	0	0	0	0	0	0	0
St/L Hosp + School Hlth	2,384	2,384	2,221	2,071	1,929	1,800	1,673
CMS Programs							
Total Medicaid (excluding Medicaid expansion)	31,037	26,762	23,746	21,626	19,010	17,174	15,751
Total Medicaid SCHIP expansion and SCHIP	331	273	196	99	28	0	0
Total CMS Programs (Medicaid, SCHIP and Medicare)	31,368	27,035	23,942	21,725	19,038	17,174	15,751
Admin. & Net Cost of Priv. Hlth Insurance	104,951	90,319	80,306	72,985	64,467	60,878	61,048
Private Funds	71,682	59,594	51,722	47,225	41,726	41,646	42,295
Consumer Payments	70,239	58,321	50,617	46,230	40,844	40,896	41,576
Out-of-pocket Payments		0	0	0	0	0	0
Pvt Health Insurance	70,239	58,321	50,617	46,230	40,844	40,896	41,576
Other Private Funds	1,443	1,273	1,105	995	882	750	719
Industrial Inplant		0	0	0	0	0	0
Other Private Revenues including Philan	1,443	1,273	1,105	995	882	750	719
Public Funds	33,269	30,725	28,587	25,760	22,741	19,232	18,753
Federal Funds	16,908	17,184	16,437	15,171	13,135	10,684	9,872
Medicare	8,008	7,289	7,589	7,340	6,283	5,084	5,262
Workers' Compensation	24	24	21	18	18	18	17
Public Assistance	10,107	9,105	8,204	7,248	6,391	4,431	4,219
Medicaid (Title XIX)	9,516	8,653	7,862	7,076	6,354	4,431	4,219

0	0	0	0
159	156	147	121
0	0	0	0
7,308	5,791	4,854	4,290
0	0	0	0
0	0	0	0
4,932	3,606	2,817	2,315
4,714	3,484	2,686	2,215
0	0	0	0
0	0	0	0
0	0	0	0
217	122	130	101
869	827	794	770
0	0	0	0
1,508	1,358	1,243	1,205
11,182	8,448	6,378	5,103
0	0	0	0
11,182	8,448	6,378	5,103
58,202	53,304	43,348	40,083
40,845	38,797	31,830	30,009
40,239	38,213	31,240	29,395
0	0	0	0
40,239	38,213	31,240	29,395
606	584	590	614
0	0	0	0
606	584	590	614
17,357	14,507	11,518	10,074
8,371	7,636	6,363	5,988
4,255	3,981	3,454	3,275
17	17	15	14
3,710	3,281	2,580	2,438
3,710	3,281	2,580	2,438

Medicaid SCHIP Expa	117	106	91	51	12	0	0	0	0	0	0	0
SCHIP (Title XXI)	473	347	250	119	25	0	0	0	0	0	0	0
Non-XIX Federal		0	0	0	0	0	0	0	0	0	0	0
Department of Defense	587	510	414	371	297	253	206	204	194	170	170	129
Maternal/Child Health	4	4	4	4	4	4	4	4	4	4	4	3
Veterans' Administration	93	92	80	74	69	68	71	75	80	83	57	53
Vocational Rehabilitation	74	71	68	65	63	62	55	51	51	53	51	47
General Hospital/Medical	0	0	0	0	0	0	0	0	0	0	0	0
Gen Hosp/Med NEC	0	0	0	0	0	0	0	0	0	0	0	0
ADAMHA/SAMHSA	68	64	53	46	36	31	35	51	56	43	27	25
Indian Health Services	5	6	5	5	5	4	4	4	4	4	4	4
O.E.O.	0	0	0	0	0	0	0	0	0	0	0	0
State and Local Funds	14,301	13,561	12,149	10,589	9,606	8,378	8,881	9,787	8,986	6,871	5,155	4,086
Temporary Disability	0	0	0	0	0	0	0	0	0	0	0	0
Workers' Compensation	6,757	6,323	5,633	4,886	4,400	4,811	5,323	5,169	4,984	4,082	2,823	2,099
Public Assistance	7,352	7,050	6,334	5,525	5,035	3,395	3,394	4,459	3,848	2,639	2,189	1,852
Medicaid (Title XIX)	7,094	6,854	6,184	5,451	5,019	3,395	3,394	4,459	3,848	2,639	2,189	1,852
Medicaid SCHIP Expa	48	44	36	20	5	0	0	0	0	0	0	0
SCHIP (Title XXI)	210	152	114	54	12	0	0	0	0	0	0	0
Non-XIX State/Local	0	0	0	0	0	0	0	0	0	0	0	0
General Assistance	0	0	0	0	0	0	0	0	0	0	0	0
Maternal/Child Health	169	166	160	156	150	152	146	141	137	132	128	122
Vocational Rehabilitation	23	23	22	22	21	20	19	17	17	18	15	14
St/L Hosp + School Hlth	0	0	0	0	0	0	0	0	0	0	0	0
CMS Programs												
Total Medicaid (excluding Medicaid expansion)	16,610	15,507	14,046	12,529	11,373	7,825	7,613	8,696	7,558	5,920	4,769	4,290
Total Medicaid SCHIP expansion and SCHIP	848	648	492	244	54	0	0	0	0	0	0	0
Total CMS Programs (Medicaid, SCHIP and Medicare)	25,464	23,443	22,127	20,113	17,680	13,809	12,874	13,144	11,813	9,901	8,223	7,565
Public Health Activity	51,159	48,325	45,817	43,728	37,997	35,439	32,916	31,430	30,009	27,219	24,845	22,447
Federal Funds	7,041	5,298	4,847	4,525	4,030	3,924	3,753	3,650	3,626	3,144	2,914	2,595
State/Local Funds	44,118	43,027	40,969	39,202	33,967	31,515	29,164	27,781	26,382	24,075	21,931	19,852
Research	34,307	31,495	28,777	23,374	20,535	18,717	17,833	17,094	16,252	15,587	15,048	13,871
Private Funds	2,691	2,691	3,401	2,098	1,975	1,586	1,610	1,398	1,444	1,375	1,183	1,091

Business	0	0	0	0	0	0	0	0	0	0	0	0
Other Private Revenues Including Philan.	2,691	2,691	3,401	2,098	1,975	1,586	1,610	1,398	1,444	1,375	1,183	1,091
Public Funds	31,617	28,804	25,375	21,276	18,560	17,131	16,224	15,696	14,808	14,213	13,865	12,780
Federal Funds	27,419	24,984	21,906	18,195	15,543	14,338	13,563	13,199	12,510	12,094	11,876	10,890
State/Local Gov't	4,197	3,820	3,469	3,081	3,017	2,792	2,661	2,496	2,298	2,119	1,988	1,890
Construction	22,366	19,153	19,218	17,555	17,716	18,522	16,396	15,484	16,218	16,202	14,870	13,395
Private Funds	17,142	14,661	14,202	13,302	13,556	13,327	11,593	11,068	12,065	12,280	11,293	10,383
Business	16,035	13,714	13,276	12,445	12,686	12,459	10,835	10,346	11,284	11,490	10,565	9,719
Other Private Revenues Including Philan.	1,106	947	926	858	869	868	758	722	781	790	727	664
Public Funds	5,224	4,492	5,016	4,253	4,160	5,195	4,803	4,416	4,153	3,922	3,577	3,012
Federal Funds	835	700	761	882	1,040	1,287	1,192	1,072	882	935	784	726
State/Local Gov't	4,390	3,792	4,254	3,370	3,121	3,908	3,611	3,344	3,271	2,987	2,793	2,286

Managing Low Back Problems in Adults

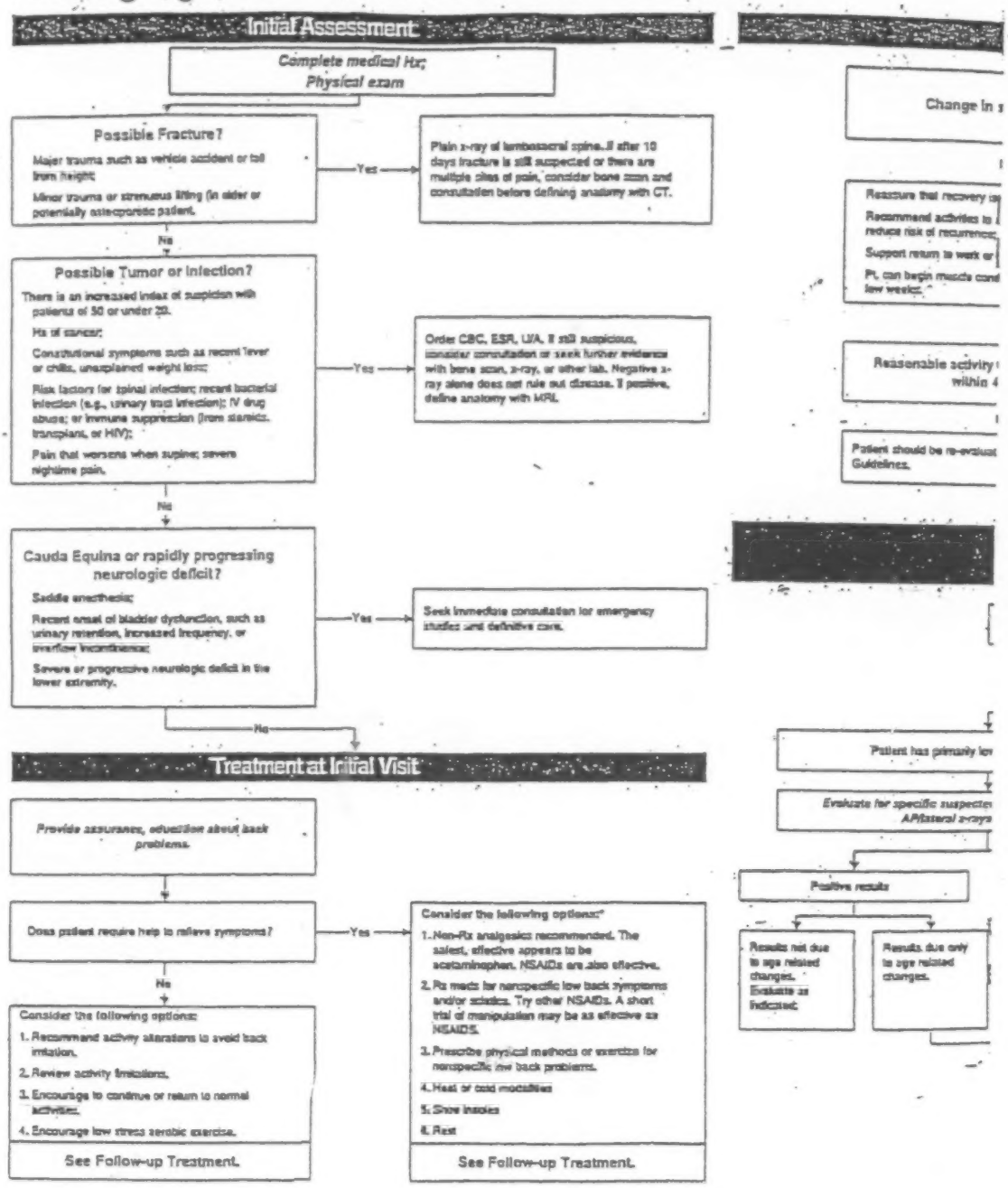
CLINICAL PRACTICE GUIDELINE SERIES

TRIGON

Trigon BlueCross BlueShield

TR11140544

Managing Low Back Problems in Adults



*Not all contracts cover manipulation, physical methods, exercise or shoe inserts

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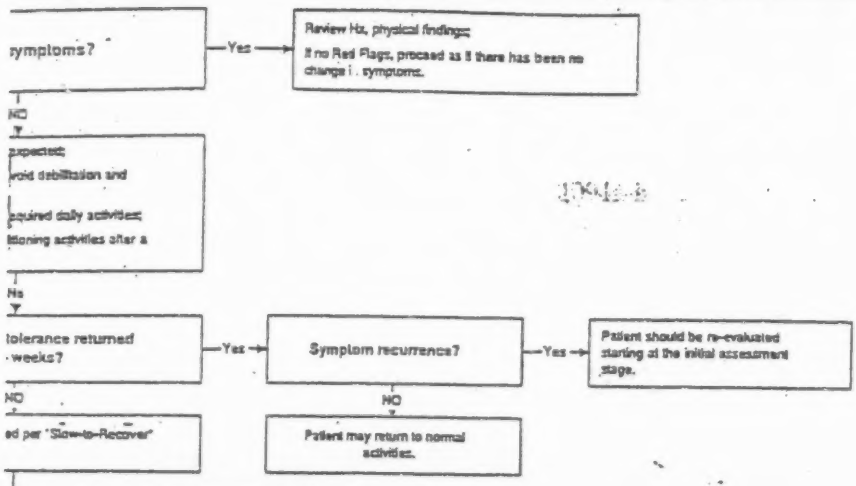
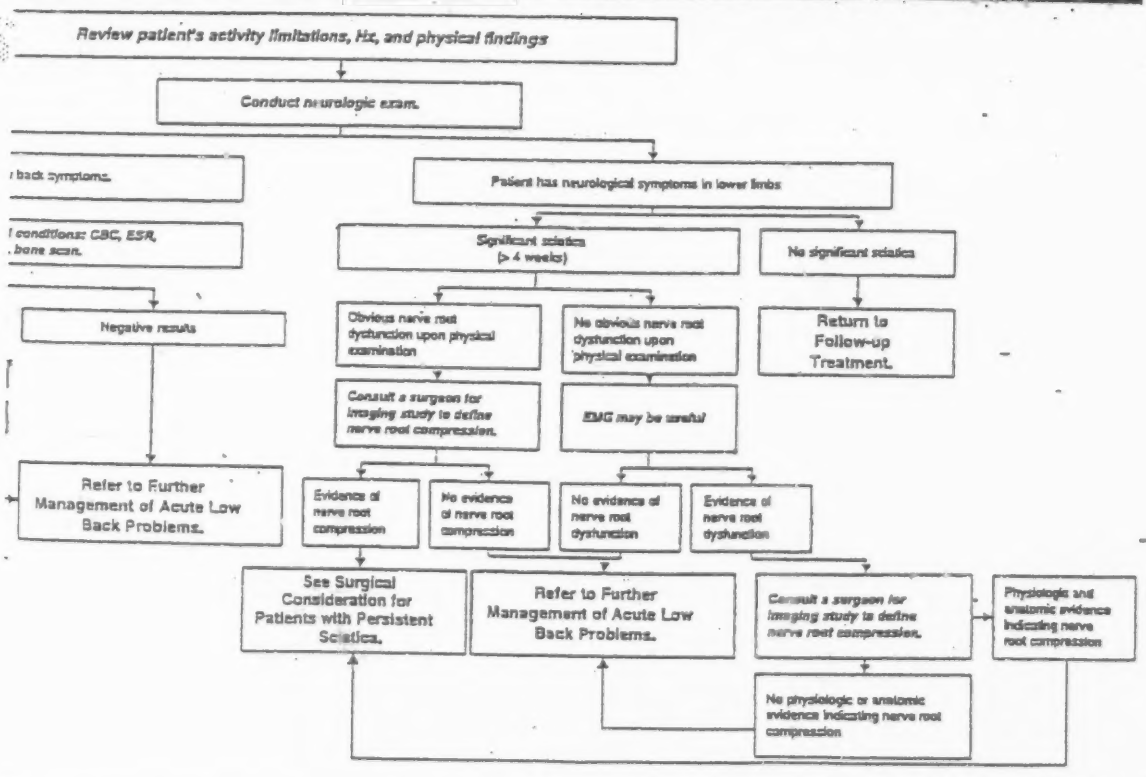
Follow-up Treatment



Evaluation of the Slow-to-Recover Patient
(symptoms > 4 weeks)



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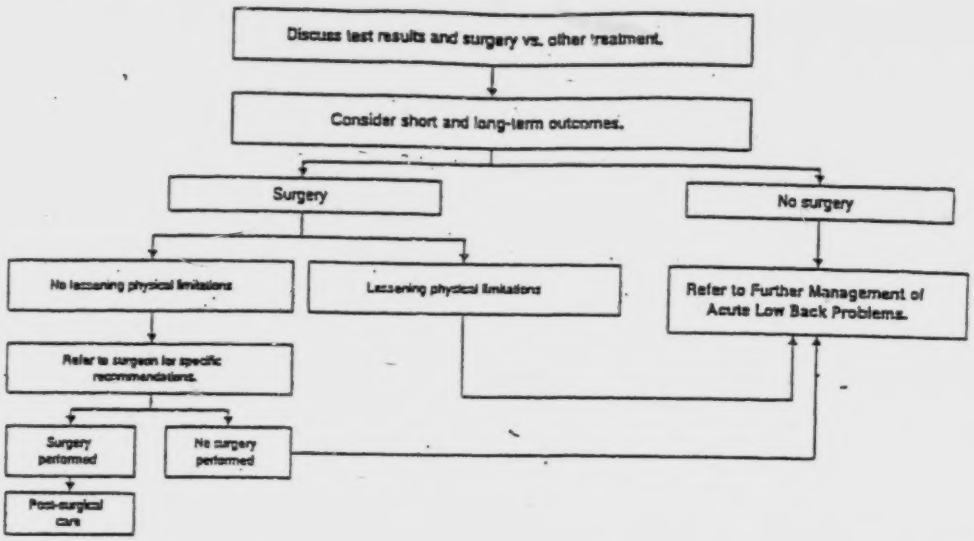
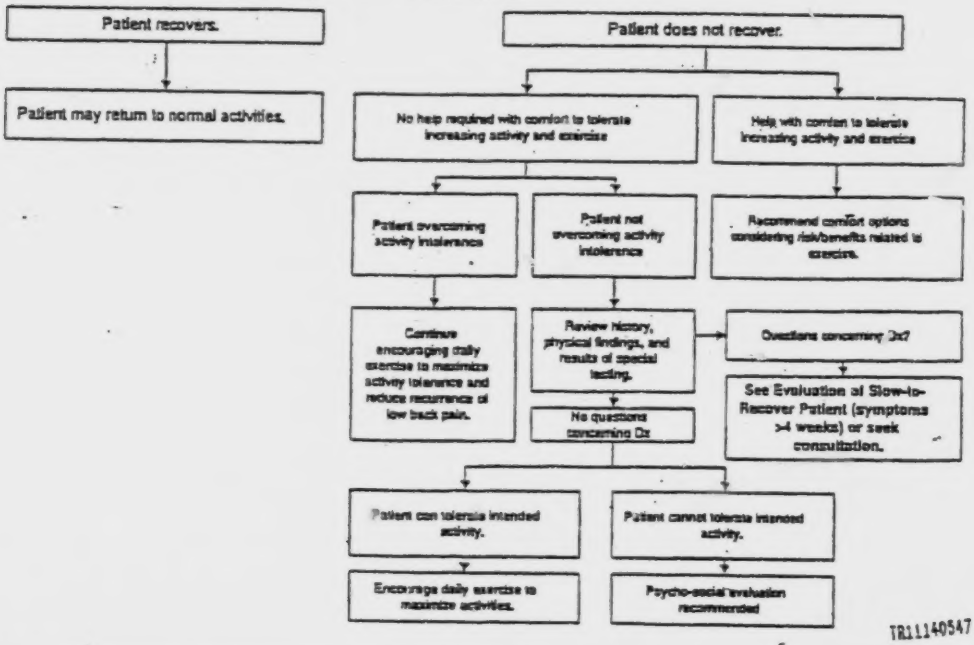
Surgical Considerations for Patients with Persistent Sciatica



Further Management of Acute Low Back Problems

General care following surgery or special studies:

- For adult patients with back-related activity limitation of more than 4 weeks but less than 3 months duration, see "Evaluation of Slow-to-Recover Patient (symptoms >4 weeks)" and "Surgical Consideration for Patients with Persistent Sciatica."
- Assure patient and establish safe exercise plan to build tolerance for intended activity.



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Trigon Blue Cross Blue Shield's Clinical Practice Guideline Series

Managing Acute Low Back Problems

The Medical Forum is pleased to publish Trigon Blue Cross Blue Shield's clinical practice guidelines for managing acute low back problems. These guidelines have been adapted from the Agency for Healthcare Policy and Research (AHCPR) and are approved and endorsed by Trigon's Managed Care Advisory Panel. Trigon's HMOs are finalizing their approval of these guidelines with the intention of creating continuity of guidelines amongst all of Trigon's managed care products.

The AHCPR defines acute low back problems as "activity intolerance due to lower back or back-related symptoms of less than 3 months duration".[1] These recommendations are intended to help the clinician assess common diagnostic and therapeutic interventions for acute low back problems. No sequential approach or clinical pathway for individual patients is implied.

Ninety percent of patients with acute low back problems, as defined here, spontaneously recover activity tolerance within one month. The approach to a new episode in a patient with a recurrent low back problem is similar to that of a new acute episode.

The findings and recommendations included in this guideline define a paradigm shift away from focusing care exclusively on the pain and toward helping patients improve activity tolerance. The guideline provides information on the detection of serious conditions that occasionally cause low back symptoms (conditions such as spinal fracture, tumor, infection, cauda equina syndrome, or non-spinal conditions). However, treatment of these conditions is beyond the scope of this guideline. In addition, the guideline does not address the care of patients younger than 18 years of age or those with chronic back problems (back related activity limitations of greater than 3 months' duration).

The initial assessment stage of the guideline should include two key components: a focused medical history and physical examination. Here are some recommendations for each.

The Focused Medical History

A patient's estimate of personal activity intolerance due to low back symptoms contributes to the clinical assessment of the severity of the back problem, guides treatment, and establishes a baseline for recommending daily activities and evaluating progress. It should include the following:

- Patient's description of present symptoms and limitations using pain drawings and visual analog pain-rating scales;
- The duration of symptoms;
- A history of previous episodes.

The Physical Exam

The examination is mostly subjective since patient response or interpretation is required for all parts except reflex testing and circumferential measurements for atrophy. It should include the following:

- General observation of the patient;
- Regional back exam;
- Neurological screening
  - —test for muscle strength
  - —circumferential measurements of the calf and thigh bilaterally to detect muscle atrophy
  - —Reflex testing
  - —Sensory examination;
- Testing for sciatic nerve root tension
  - —straight leg raising test
  - —sitting knee extension test.

In the absence of red flags (see guideline), diagnostic testing is not clinically helpful during the first 4 weeks of symptoms when spontaneous recovery is expected.

Reference

[1]Public Health Service, Agency for Healthcare Policy and Research (1994). Acute Low Back Problems in Adults: Assessment Treatment. AHCPR Publication No. 95-0643. Rockville, MD.

TR11140548

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In The
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OFFICE OF THE CLERK

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George P. McAndrews
Counsel of Record
Steven J. Hampton
Patrick J. Arnold, Jr.
Sharon Hwang
James P. Murphy
Peter J. McAndrews
Ronald A. Dicerbo
MCANDREWS, HELD & MALLOY, LTD.
34th Floor
500 West Madison Street
Chicago, IL 60661
(312) 775-8000

Thomas R. Daly
ODIN, FELDMAN, & PITTLEMAN, P.C.
9032 Lee Highway
Suite 1100
Fairfax, VA 22031
(703) 218-2100

William G. Shields
THORSEN & SCHER
3810 Augusta Ave.
Richmond, VA 23230
(804) 359-3000

Counsel for Petitioners

THE LEX GROUP ♦ 1108 East Main Street ♦ Suite 1400 ♦ Richmond, Virginia 23219
(804) 644-4419 ♦ (800) 856-4419 ♦ Fax: (804) 644-3660 ♦ www.thelexgroup.com

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PROTECTIVE ORDER

MANAGED CARE ADVISORY PANEL

October 25, 1995
4:00 - 6:30 p.m.

The meeting of the Managed Care Advisory Panel was held on October 25, 1995. Those present were:

Dr. Richardson Grinnan, Trigon BCBS Chief Healthcare Officer
Dr. Larry Colley, Trigon BCBS V/P Medical Polity
Dr. Michael Hattwick, Va. Society of Internal Medicine
Dr. Robert Williams, Dept of FP, MCV
Dr. Geoffrey Viol, American College of Physicians
Dr. Verdain Barnes. Dept of IM, EVMS
Dr. Willett LeHew, Vt. Chapter of ACOG
Dr. Latane Ware, Medical Society of Virginia
Dr. Stuart Salem Va. Chapter of *AAFP*
Dr. Peter Nord, Peninsula Health Care
Dr. Tony Pelonero, Trigon Mental Health
Dr. James Carney. Trigon BOBS
Ms. Pat Maddox, Trigon BOBS
Ms. Pamela Roberts, Trigon BCBS

Absent: Dr. Torn Massaro, UVA

TOPIC Minutes of Previous Meeting

DISCUSSION Motion to Approve Minutes by Dr. LeHew.

ACTION Minutes Approved.

[REDACTED]

[REDACTED]

TOPIC Approval of Practice Guidelines from Regional Committees

1. Low Back Pain

2. Otitis Media with Effusion

3. Pediatric Asthma

DISCUSSION Dr. Ware: not comfortable with how well they have been reviewed, especially for referral to specialists.

Dr. Hattwick: we need to go over these one by one--are these meant to be referral guidelines"

Dr. Colley: yes, they are referral guidelines.

Dr. Hattwick: we should emphasize that they are referral guidelines, if they are.

Dr. Grinnan: the guidelines are a baseline of what a primary car physician should manage in these categories, and we are reviewing them regionally.

Dr. Hattwick: operationally, these are a mixture of management and referral guidelines.

[REDACTED]

[REDACTED]

ACTION Amend Plan:
To include Primary Care physician; to consider the role of primary care in guidelines being developed

Unanimously adopted by Committee.

Otitis media with effusion will go back to Committee for clarification.

Meeting Adjourned at 6:30 p.m.

Meetings in the first and second quarters of 1996 deferred due to lack of action items for agenda.

Next Meeting, July 24, 1996 at 6 p.m.

approved July 24, 1996

TRIGON
Trigon BlueCross Blue-Shield

HIGHLY CONFIDENTIAL
PURSUANT TO
PROTECTIVE ORDER

J. Lawrence Cathy, M.D.
Vice President,
Corporate Medical Policy

May 2, 1996

Craig N. Bash, M.D.
Laurel Diagnostic Imaging
9811 Mallard Drive, Suite 102-104
Laurel, Maryland 20708-3 199

Dear Dr. Bash:

Thank you for your letter of April 5, 1996, regarding Trigon's back pain algorithm. In creating this algorithm, Trigon did not intend to address all issues related to backs. Rather, Trigon sought to cast the Agency for Health Care Policy and Research (AHCPR) guidelines into a user-Friendly format. We sought to maintain consistency with AHCPR on all clinically material issues.

It is worth noting that the AHCPR guidelines have a primary care orientation. They are intended to help primary care providers make decisions about treatment, consultation and the ordering of diagnostic tests. Trigon's internal review process included consultation with, and approval by representative appointed by the Virginia chapter of the American Academy of Pediatrics, the Virginia chapter of the American Academy of Family Physicians, the Virginia Society of Internal Medicine, the Virginia chapter of the

American College of Physicians, the Virginia chapter of the American College of Surgeons, the Virginia Obstetrical and Gynecological Society, the Medical Society of Virginia, the University of Virginia School of Medicine, Eastern Virginia Medical School and the Medical College of Virginia. None were neuroradiologists.

I sincerely appreciate your reading the Medical Forum and taking the time to write. When the American Society of Neuroradiologists completes its algorithm, I would be happy to receive a copy and to have it considered by an appropriate advisory committee. Thank you for your correspondence with Trigon.

Sincerely,

/s/_____

JLC/mea(bash.ltr)

cc: Hudson Moore, Editor, Medical Forum

2015 Staples Mill Road Post Office Box 27401 • Richmond. Virginia 23279 • 804-354-2104 • Fax 804-354-3829

Trigon Blue Cross *Blue* Shield is the trade name of Blue Cross and Blue Shield of Virginia An Independent Licensee of the Blue Cross and Blue Shield Association

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Ronald A. Dicerbo
MCANDREWS, HELD & MALLOY, LTD.
34th Floor
500 West Madison Street
Chicago, IL 60661
(312) 775-8000

Thomas R. Daly
ODIN, FELDMAN, & PITTLEMAN, P.C.
9032 Lee Highway
Suite 1100
Fairfax, VA 22031
(703) 218-2100

William G. Shields
THORSEN & SCHER
3810 Augusta Ave.
Richmond, VA 23230
(804) 359-3000

Counsel for Petitioners

THE LEX GROUP ♦ 1108 East Main Street ♦ Suite 1400 ♦ Richmond, Virginia 23219
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THIRD CORRECTED EXPERT WITNESS STATEMENT ON ECONOMIC ISSUES ON BEHALF OF PLAINTIFFS AMERICAN CHIROPRACTIC ASSOCIATION AND OTHERS

Leonard G. Schifrin, Ph. D.
Chancellor Professor of Economics, Emeritus
College of William and Mary
Williamsburg, Virginia

Clinical Professor of Preventive Medicine, 1982-1992
Medical College of Virginia -
Richmond, Virginia

My name is Leonard G. Schifrin. I reside at 163 Devon Road, Williamsburg, Virginia. I was a Professor of Economics, specializing in health care economics and health care policy, at the College of William and Mary, Williamsburg, Virginia, until my retirement from teaching in 1998. I received my bachelor's degree in economics from the University of Texas, Austin, in 1954, rny master's degree in economics, also from the University of Texas, in 1958, and my doctorate in economics from the University of Michigan in 1964.1 have had numerous academic affiliations during my career before and while I served at William and Mary. One such affiliation was as Clinical Professor of Preventive Medicine at the Medical College of Virginia, in Richmond, from 1982 until 1992, where I gave lectures and seminars on all aspects of health care economics and policy. Currently I work in litigation and other matters within my specialties on a consulting basis. My full academic and consulting backgrounds are in my Curriculum Vitae, which is attached to this statement. In this case I am being remunerated at a rate of $200 per hour, and expenses.

I. COMPETITION IN THE TREATMENT OF BACK PAIN

This statement focuses on the provision of medical services by chiropractors, particularly those services also provided by other practitioners such as medical physicians and surgeons and osteopaths. These different providers stand as alternative sources of treatment, particularly for back pain but also for other ailments stemming from problems of the musculoskeletal system, and as such they are correctly viewed by patients as substitutes or competitors in the provisiori of care for such problems.

Competition between and within alternative providers has become a common and desirable — though not universal — feature of the modem medical scene in the United States and has played a major role in containing health care costs. Although total health care costs are large and growing quickly, nonetheless, they are substantially lower than they would be without such competition. Examples of competition between different types of providers are plentiful. For example, there is competition in the prescription of corrective eyewear between ophthalmologists and optometrists, and in providing corrective eyewear between optometrists and opticians. Another example is the competition in the provision of anesthesiological services between anesthesiologists and nurse anesthetists. There is competition in the provision of diagnostic tests between hospital laboratories, independent laboratories, and physicians' in-office laboratories. Competition within provider categories also is seen, such as the competition in the provision of primary care physician services between physicians working independently, in small and large group practices, in hospital clinics, in free standing hospital outreach offices in shopping centers and elsewhere. There is competition in the provision of surgery between hospital operating rooms and specialized surgicenters. In other words, competition — or at least the

potential for competition — in the provision of medical services is pervasive. It is this competition that is the lifeblood of "value for money" in choosing medical care, and, when competition is free to function, it drives the system to work for the benefit of those who pay for health care — individual households, private employers, and governments — and those of us who need it, namely, everyone.

The specific issue at hand is the role of chiropractors in this competition, particularly vis-a-vis medical physicians and surgeons and doctors of osteopathy in the treatment of one of the most common ailments for which patients seek medical care, back pain. Back pain afflicts almost everyone sometime during their life. By many estimates it is the second most frequent cause for seeking care, after upper respiratory problems, and the most common reason for young adults to seek care. Hence, in economists' terms, the treatment of back pain represents a large economic market.

The essential first question is how chiropractic compares as a viable alternative or competitive ' mode in meeting this large need for the treatment of back pain. Specifically, what does the published evidence in the professional health care literature reveal about the efficacy and cost of treatment of back pain by chiropractors compared with other professional providers. In answering that question we turn first to research in the period before 1992, and then to research in the period afterward.

A. Professional Studies of the Efficacy, Cost, and Cost-Effectiveness of Chiropractic Treatment of Musculoskeletal Injury, Particularly Soft-tissue Injury of the Lower Back (Back Pain): Up to 1992.

1. The Study for the Virginia Chiropractic Association

Two comprehensive reviews of the professional literature addressing comparisons between chiropractic and other types of treatment for back pain occurred almost simultaneously. One is a study I performed under contract with the Virginia Chiropractic Association (VCA), completed in 1992.[1] The other is a major study by the RAND Corporation published slightly earlier. The following is the summary (pp. 69-71), verbatim, of the results of the literature review in my 1992 study for the VCA.

The U.S. and Foreign Studies: Summary,

All told, 22 literature surveys or research studies and one "inquiry" have been reviewed here. These have covered two time periods, the "earlier" period before 1980, the "recent" period after 1980. The data studies have covered 14 states and

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[1] MANDATED HEALTH INSURANCE COVERAGE FOR CHIROPRACTIC TREATMENT: AN ECONOMIC ASSESSMENT, WITH IMPLICATIONS FOR THE COMMONWEALTH OF VIRGINIA. Leonard G. Schifrin, Ph. D., Virginia Chiropractic Association, January 1992. This study was conducted independent of any litigation, including this case, involving the chiropractic profession. Further, it was made clear to the VCA that I was not their "hired gun" agreeing before the fact to support their position in the issue at hand; rather, I would systematically review and objectively analyze the published literature on chiropractic efficacy and cose, and set forth my results exactly as they emerged.

two foreign countries, and the literature surveys have included still others.

These materials have considered, in total, eight different dimensions of the cost and efficacy of chiropractic treatment of low back pain. The cost measures have included total case costs, total provider payments, total worker indemnity payments to compensate for wage loss, and treatment frequency; the efficacy or outcomes measures have included the duration of work loss, the period of disability, pain relief, and patient satisfaction with treatment.[2] Of course, each study is unique, in its design and methodology, including location, case selection, time span, and cost and efficacy criteria. -They do not relate as closely to each other as pieces in a jigsaw puzzle, but they do bear generally on the same questions and contribute evidence to their answers.

In the 14 state studies in the pre-1980 period, chiropractic compares favorably with medical doctors in the treatment of low back pain. Only in one facet of one study, indemnity payments in the 1974-1975 Oregon study, does chiropractic not rank more favorably than medical treatment. *In about 35 other comparisons in these 14 studies and the two general surveys, the results of chiropractic treatment exceed those of medical care.*

In the four studies in the post-1980 period, covering West Virginia, Iowa, Florida, and Oregon, chiropractic also fares well, although not quite so unanimously. In the Iowa and Florida studies, chiropractic surpasses medical treatment in the efficacy measures; on the other hand, chiropractic provider costs are higher, but when all case treatment costs are taken into account, total case costs for D.C. care are seen to be lower. One study, in Oregon, produced mixed, "unremarkable" results, and another, the Greenwood study in West Virginia, was unique among all examined here, finding chiropractic more costly and less effective in the four measures employed.

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[2] In all cases where italics appear in the text of this statement they have been added for emphasis.

Every study, favorable to chiropractic or not, admittedly is imperfect, sometimes seriously. *However, within their limitations, individually – except for the Greenwood study – and together they are more favorable to chiropractic than to medical practitioners, in terms of both cost and effectiveness, in the treatment of low back pain associated with sprains and strain.*

The two foreign studies, one the MRC Study in Great Britain, the other the Report of the Commission of Inquiry in New Zealand, are both supportive of chiropractic. The' British study strongly favors chiropractic treatment over hospital-based physiotherapy, and the New Zealand report gives chiropractic a broad stamp of approval, advocating its inclusion in both their national health care and disability insurance systems. Again, these conclusions are to be taken within the limitations of their respective contexts, *but they, too, are more supportive of chiropractic than alternative sources of care, on these crucial counts of cost and effectiveness*

2. The RAND Study

Although its scope is substantially broader, The RAND Corporation's Literature Review Summary[3] is in essential agreement with the conclusions of the VCA Study. Notably, RAND's statement on "Efficacy" (p.v) reads as follows:

> The literature on the efficacy of spinal manipulation is of uneven quality. While many studies are randomized controlled trials, there is a great diversity in the initial selection and evaluation of patients for study, assignment of those patients to spinal manipulation or a control treatment, the type of manipulation given, the type of control treatment given, and

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[3] THE APPROPRIATENESS OF SPINAL MANIPULATION FOR LOW BACK PAIN: Project Overview and Literature Review. Shekelle et al., RAND Corporation, Santa Monica, CA, 1991.

> the method of assessing a response. Given that caveat, *support is consistent for the use of spinal manipulation as a treatment for patients with acute low-back pain and an absence of other signs or symptoms of lower limb nerve-root involvement.* Support is less clear for other indications, with the evidence for some *insufficient* (acute and subacute low-back pain with sciatica, acute and subacute low-back pain with minor lower limb neurological findings, most types of chronic back pain), while the evidence for others is *conflicting* (acute low-back pain with sciatica and minor lower limb neurological findings, subacute low-back pain without sciatica, and chronic low-back pain without sciatica).

Note that in none of these summary review statements is there a negative finding for the efficacy of chiropractic treatment.

B. Reports and Research: After 1992:

1. Agency for Health Care Research and Policy ("AHCPR")

An especially important policy statement on the efficacy of chiropractic treatment of low back problems is the Report by the Agency for Health Care Research and Policy of the Department of Health and Human Services, "ACUTE LOW BACK PROBLEMS IN ADULTS: CLINICAL PRACTICE GUIDELINES."[4] This report is based on analyses of literally hundreds of studies and overviews and its conclusions

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[4] U.S. Department of Health and Human Services, Washington, DC, December 1994. U.S. Department of Commerce, National Technical Information Series.

represent what has been referred to as "a paradigm shift" in the treatment of back pain. (This paradigm shift is discussed in detail in Part II of this Statement.)

Excerpts from the AHCPR Report compare the *usefulness* of *medications* and *manipulation:*

a. The AHCPR finds that some types of *medications* are useful in the treatment of low back pain, but there may be *risks* in their use such as adverse side effects, drowsiness, and dependency, while other types of medications are not recommended (pp.26-34.)

b. As to spinal manipulation[5] in treating low back problems, the Report states (p.34), "Manipulation can be helpful for patients with acute low back problems without radiculopathy when used within the first month of symptoms. (Strength of Evidence = B)"[6]

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5 The AHCPR defines "manipulation" in its medical sense, as follows: "... For this guideline, manipulation is defined as *manual therapy in which loads are applied to the spine using short or long lever methods. The selected joint is moved to its end range of voluntary motion, followed by application of an impulse loading. The therapeutic objectives of manipulation include symptomatic relief and functional improvement*" (pp. 34-35.)

6 "Strength of Evidenced" means the finding is supported by "Moderate research-based evidence (one relevant, high-quality scientific study or multiple adequate scientific studies")

c. Further, the Report's "Findings and Recommendations" as summarized in the Abstract (p. iii) brings together these views on medication and manipulation in regard to pain relief thus: "*Relief of discomfort can be accomplished most safely with nonprescription medication and /or spinal manipulation.*"

Accordingly, all three of these statements appear to put nonprescription medication and spinal manipulation on an equal footing in their effectiveness in treating back pain.

d. However, a very important additional conclusion, referring only to manipulation, is to be found (p.36) under the heading "Summary of Findings." It reads, "...For patients with acute low back pain symptoms without radiculopathy, the scientific evidence suggests spinal manipulation is effective in reducing pain and perhaps speeding recovery within the first month of symptoms..." In other words, improved functional capability, not just the alleviation of symptomatic pain, may result from manipulation. No similar statement is to be found for the use of nonprescription medication, or any other treatment.

This view of the AHCPR is strengthened again by reference to the professional literature. The AHCPR continues (p.35) "A meta-analysis of the remaining seven studies also showed significant short-term effects of manipulation in hastening recovery from low back problems. Another meta-analysis, based on 23 randomized controlled trials of manipulation and mobilization, came to a similar conclusion."

Clearly, then, the compelling conclusions of this Report by the preeminent governmental health care research agency are:

- *chiropractic manipulation is a first line of treatment for low back pain not associated with "red flag" diagnosis such as "tumor, infection, or significant trauma," and*

- *unlike medication, helps in restoring the patient's functional capability, thus reducing the duration of disability.*[7]

1. Additional Research Studies

Other current and noteworthy studies continue to strengthen the case for chiropractic treatment of back pain, with emphasis on its cost-effectiveness and the savings thus attained. Two such studies are Snook and Hendrickson, "An Actuarial Analysis of the Impact of Chiropractic Care on the Costs of Medical Care for Patients with Common Spinal Diagnoses",[8]

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[7] It should be noted that Trigon publishes a "Clinical Practice Guideline Series," titled quite closely to AHCPR's "Clinical Practice Guidelines." In the Trigon publication MANAGING LOW BACK PROBLEMS IN ADULTS, in the protocol under the heading "Treatment at Initial Visit," the last sentence of option 2 reads, "A short trial of manipulation may be as effective as NSATDS..." in relieving symptoms, implying that NSATD medications are the standard which manipulation may or may not approach. This statement is not at all in the spirit of the AHCPR statement that equates the two treatments in regard to pain relief and reads, again, "Relief of discomfort can be accomplished most safely with nonprescription medication and /or spinal manipulation." Further, the Trigon Guidelines make no mention of AHCPR's finding that there may be improved *functional capability* resulting from manipulation. (This point will be revisited in PART II, p.10 of this brief.)

[8] Milliman USA, October 11, 2001.

and "Trends in Chiropractic Treatment of Workers' Compensation Claimants in the State of Florida."[9]

Snook and Henderson conclude:

> ...patients with common spinal diagnoses...who seek chiropractic care have materially lower health care costs than those who do not[10]

In the Florida report the authors conclude:

> Based on estimated savings per claim, dramatic savings *(possibly into the billions of dollars)* may be possible with increased workers' compensation claimant access to chiropractic treatment for specific low back and other musculoskeletal conditions.[11]

These two studies thus ratify an important point made in my 1992 study for the Virginia Chiropractic Association, namely, that the expansion of the use of chiropractic treatment not only does not increase society's total spending on health care, but is highly likely to constrain and even reduce it by providing a more effective treatment at lower cost for a very common physical problem.

Completing this review of the most prominent professional literature on the treatment of back pain, I requested from Anthony L. Rosner, Ph. D., Director of Research and Education for the Foundation for Chiropractic Education and Research, the leading studies, in terms of their methodological

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9 Submitted to Ms. Debra Brown, Chief Executive Officer Florida Chiropractic Association by MGT of America, Tallahassee, Florida, January 28,2002.

10 P.8

11 P.iv

rigor, on chiropractic cost-effectiveness, of the past decade. The 10 studies he submitted are listed in Appendix A of this Statement.

Upon review of these studies, these conclusions emerge:

a. The medical and statistical rigor of these studies has reached an impressive level, and the findings they provide are less subject to qualification than many preceding studies.

b. Studies on the outcomes of chiropractic treatment now include disabilities other-than back pain, particularly headache, neck pain, widespread musculoskeletal disorder, hemiated disks, carpal tunnel syndrome, and whiplash.

c. Recent research on manipulation continues to find it effective in the treatment of low back pain problems, both in relieving pain and restoring functional mobility.

d. Further, studies on adverse outcomes of manipulation indicate that serious complications
are extremely rare.

Thus, while the recent literature in regard to the treatment of low back pain by manipulation is more rigorous and far reaching, as a whole, than earlier studies, the conclusions of the earlier research again are strongly validated, namely, *that manipulation is an effective and economical intervention for such problems.* Further, the recent evidence also finds manipulation to be a *highly safe* treatment.

Accordingly, based on the large quantity of reports, studies, and overviews covering the periods before and after 1992, my professional conclusions on chiropractic manipulation in the treatment of back pain are the following:

> *In virtually all measures of beneficial outcomes and low costs, chiropractic treatment of back pain compares highly favorably with other sources and types of treatment, including medical management, surgery, bed rest, osteopathy and physiotherapy. With near unanimity, the evidence, viewed piecemeal or together in a broad picture, strongly supports chiropractic as a treatment of choice for this very common and costly ailment.*
>
> *The practice guidelines issued by the leading governmental health care policy and research agency, AHCPR, provide strong support for the use of spinal manipulation as a first line of treatment for non-traumatic back pain, with additional indication of its effectiveness in improving functional mobility.*
>
> *Chiropractic manipulation in treating back pain is a highly safe form of therapy.*
>
> *This evidence supports the view that, in a free, open, and competitive market for the treatment of back pain, chiropractors would be highly effective competitors vis-à-vis medical physicians and surgeons, osteopaths, physical therapists, and other medical professionals*

II. RESTRAINTS BY TRIGON AND MEDICAL PHYSICIANS ON THE POTENTIAL COMPETITION FROM CHIROPRACTORS IN THE TREATMENT OF BACK PAIN

Although chiropractic treatment of back pain is a demonstrated effective and economical alternative compared

with other treatments, and chiropractors thus are potentially strong competitors with other types of providers in treating back pain, substantial anti-competitive restraints have been placed in the way of their equitable participation in this large market.

Anti-Competitive Market Power

Because most patients are covered by health insurance, providers' fees for patient services are largely determined by a few, large payers, whether they are called pre-payment plans or insurers.

The market power of these payers in the provision of treatment for back pain is such that the terms of transactions – which providers offer what services at what prices – are not independently determined by free competition and free choice, but result from the arbitrary decisions of large market participants. Trigon, as a dominant payer for health and medical services in Virginia, has exercised its market power, in combination with organizations of medical physicians in Virginia, to harmfully restrain the participation of chiropractors in the' provision of treatment for back pain for Trigon-insured patients, for the economic protection of medical physicians.

The methods employed by Trigon and the organizations of medical doctors who treat back pain are A: setting low limits or "caps" on how much Trigon will pay for a patient's chiropractic treatments in a given year, B: unreasonably low reimbursement for chiropractic procedures other than manipulation (for example, evaluation and management and X-rays) for back pain, and C: actions to curtail referrals to chiropractors by medical physicians. The aim and effect of these actions are to restrain competition bv reducing the role of chiropractors in the treatment of back pain and shift the demand for their services to medical doctors.

A. Caps

Reimbursement caps or limitations, if set at restrictive levels, can impose heavy financial penalties on patients and also on chiropractors. Trigon has imposed a cap on payments for spinal manipulation of $500 per year per insured individual. In other words, Trigon will pay a total of no more than $500 to any and all chiropractors for therapy for a Trigon-covered mdividual in a given year regardless of how much treatment is necessary to remedy the problems suffered by that person. Once this cap is reached, patients who continue to seek chiropractic treatment of any sort must pay 100% out-of-pocket, with no further insurance coverage. Obviously, this will curtail the demand for chiropractic services, redirecting patients to other types of providers such as medical doctors at the outset or during their chiropractic treatment, or perhaps causing patients to halt their therapy entirely when the $500 limit is reached.

Caps thus may pose a serious constraint imposed by Trigon on chiropractors' ability to compete with medical doctors in this large market.

B. Under-reimbursement

1. Discounting Payments to Chiropractors for Services Other Than Chiropractic Manipulative Treatment (CMT)

In an effort to make reimbursement payments for different health care procedures paid for under Medicare and other government health programs bear reasonable relationships to each other, and to offer a model useful to private insurers, the Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services developed a formula for estimating the relative costs of producing a wide range of such procedures. This model is called the Resource

Based Relative Value Scale (RBRVS.) These relative cost differences are intended to guide the differences in reimbursement rates paid to providers, on the principle that payment differences should reasonably relate to cost of production differences for different procedures. Treatments of spinal problems are included in this Resource Based Relative Value Scale.

Documents I have read in preparing for this case indicate that Trigon's payments to providers are calculated by multiplying RBRVS values (called RVUs, or Relative Value Units) by a monetary "conversion factor." For chiropractic services other than manipulation, however, the product of this multiplication is discounted heavily, -falling well below the rates paid to medical doctors for the same procedures. This reduction was 30% up to late November 1996, and 40% since then.

Attempting to defend these payment differentials, Trigon argues at one point that the payment to chiropractors, compared with medical doctors, for these treatments (other than manipulative therapy) for back pain is explained or rationalized by the differences in their costs of education, training, and other inputs into their services to patients, and medical physicians are entitled to their much higher payments from Trigon because of their higher costs of producing these services.

The fallacy in Trigon's argument is this: physicians, both primary care and specialists, are trained to diagnose and treat a very wide range of health care problems, while chiropractors are intensively trained in a relatively narrower range of diagnosis and treatment. It is not reasonable to include in the physicians' cost base for treating back pain all costs of their training, however far removed from back pain they might be. If only the costs incurred in preparing doctors of medicine to diagnose and effectively treat *back pain* are measured, these costs appear to be surprisingly small, given studies, testimony,

and other statements that the time spent educating physicians in treating back pain is minimal, or even zero, in the crowded medical school curriculum.

A useful analogy might be this: imagine a mechanic with a diploma attesting to his competence to treat all problems of the automobile. He has a large shop, numerous helpers, and a wide range of equipment and machinery. Next door is a mechanic who repairs only brakes, with a diploma in brake repair from an accredited technical school, perhaps one helper, and the necessary tools for repairing brakes, nothing more. Is it logical for the first mechanic to charge a higher price to repair your auto brakes because he also stands ready to diagnose and repair engines, transmissions, drive shafts, fuel systems, electrical systems, and all the other complex components of today's cars? Of course not. And perhaps, on closer examination, his actual training may not have included certain other, perhaps more cost-effective, ways to repair brakes than those he was taught in school and currently uses. The idea of paying him more to repair your brakes because of his higher total costs of training and equipment is, of course, unjustified and unfair, harmful to both your automobile and your pocketbook. And in a *competitive* market for brake repairs, such large differentials in pricing would not exist.

The other argument, that "market conditions" are to be used for determining a few reimbursement rates, is a telling one. However important competition is becoming in the broad health care scene, the market for medical services is not yet freely competitive, since, as noted, it is dominated by a few large group payers for services (such as pre-pay organizations and insurers like Trigon) and by medical doctors who do not compete openly among themselves in price and quality. Accordingly, the market conditions referred to by Trigon are the conditions of a market in which pre-payers, insurers, and medical doctors are the dominant, powerful, noncompetitive players, and chiropractors, who

want to be competitive players, are small and powerless. In such markets, the powerful actors – particularly, as in this case, when they act together – can heavily influence and largely determine what the pattern of production will be and what price tags will be attached to it. In this particular market – the treatment of back pain – the power to under-compensate chiropractors relative to doctors of medicine, (and other providers) exists. It is implemented by cooperation between Trigon and the medical doctors of Virginia acting through their professional organizations, and its effects are harmful.

2. "Leveling" Payments for CMT Services.

For manipulation services perfonned by chiropractors, Trigon has put into place another system for underpaying that can be called "levering of codes." Trigon has reduced payments for treatments in reimbursement codes 98941 and 98942 by setting these payments equal to those for code 98940, which involves less intervention and thus is of lower monetary value.

Discounting payments for non-CMT services and leveling payments for CMT services affect all chiropractic services, and together create severe under-reimbursement to chiropractors. Under-reimbursement, talcing these two forms, thus constitutes another restraint on chiropractors' equal competitive participation in the market.

C. Curtailed Referrals: the Trigon Guidelines Reexamined.

We now revisit footnote 7, p. 6 of this Statement, which reads, in its entirety, as follows:

> It should be noted that Trigon publishes a "Clinical Practice Guideline Series," titled quite closely to AHCPR's "Clinical Practice

> Guidelines." In the Trigon publication in this series MANAGING LOW BACK PROBLEMS IN ADULTS, in the protocol under the heading "Treatment at Initial Visit," the last sentence of option 2 reads, "A short trial of manipulation may be as effective as NSATDS..." in relieving symptoms, implying that NSATD medications are the standard which manipulation may or may not approach. This statement is not at all in the spirit of the AHCPR statement that equates the two treatments in regard to pain relief and reads, again, "Relief of discomfort can be accomplished most safely with nonprescription medication and /or spinal manipulation." Further, the Trigon Guidelines make no mention of AHCPR's finding that there may be improved *functional capability* resulting from manipulation.

It was indicated earlier that the widely publicized AHCPR position on the treatment of low back pain represented a major "*paradigm shift*" in the therapeutic management of this widespread health problem. This shift is *away from the management or alleviation of back pain by medical doctors using drugs, surgery, bed rest, and other approaches, to the treatment of back pain by chiropractors using manipulation,* with improved outcomes in pain relief and restoration to activity or "functional mobility." *In other words, the change in paradigm means that new treatments (manipulation) by new providers (chiropractors) with new and better results (relief of pain plus improved functional mobility) constitute the now-preferred approach to back pain.*

Further, the implication of the new paradigm is that when patients with back pain come to medical doctors, it would be in the best interest of the patient to be referred by the medical doctor to a chiropractor for manipulative therapy and related treatment.

Trigon, however, in its Clinical Practice Guideline Series Publication "MANAGING LOW BACK PROBLEMS IN ADULTS," a re-write of the ACHPR Guidelines, obfuscates this new paradigm of manipulative therapy in an attempt to neutralize the AHCPR's endorsement of chiropractic.

< "Manipulation," which in-the AHCPR report is defined in way that precisely reflects what chiropractors perform, is nowhere defined in the Trigon guidelines.

< When "manipulation" is mentioned, it is placed not on an equal footing with non-prescription medication, as in the AHCPR Report, but placed *after* "Non-rx analgesics." These drugs are mentioned as "recommended" by Trigon in "option 1" of the protocol, but "a short trial of manipulation" which "may be as effective as NSAIDS" is mentioned only afterward, in "option 2." The fact that manipulation is recommended at least equally by AHCPR thus has been totally ignored by Trigon, and any reference to "chiropractic" manipulation is avoided.

< Further, the Trigon Guidelines make no mention at all of the possibility of better outcomes or results in terms of improved functional mobility if patients are, referred to chiropractors for treatment with manipulation.

This revised treatment protocol in the Guidelines for Managing Low Back Problems in Adults, approved by representatives of Trigon and the medical doctors of Virginia acting together (in Trigon's words, "in consultation"), is an attempt to prevent the referrals by medical doctors to chiropractors implicit in the new paradigm. It is still one more restraint, arguably the most serious, placed on

chiropractors' equal competitive participation in the market, posing harm to patients and losses to chiropractors, for the gain of medical doctors.

III. ECONOMIC AND HEALTH LOSSES RESULTING FROM THE RESTRAINTS PLACED ON CHIROPRACTORS' ABILITY TO COMPETE EQUALLY IN THE TREATMENT OF BACK PAIN

Chiropractors. The constraints identified and enumerated above impose economic losses, possibly very large, on chiropractors by reducing their incomes from professional practice. The monetary limitations and the reductions in referrals have negative impact on the number of patients, thus substantially reducing chiropractors' incomes from professional practice. Patients may be well aware that chiropractic treatment is less expensive and more efficacious than medical management, hospitalization, or surgery, but recognize that their out-of-pocket costs may be lower if at some point in their treatment, even at the outset, they turn to a different type of provider whose services are more generously covered in their insurance plan. Accordingly, any reductions in the number of patients because of treatment and financial limitations under Trigon insurance coverage necessarily result in economic loss to the excluded provider, in this case chiropractors.

Underpayment for services for insured-covered patients who do pursue treatment by chiropractors further reduces chiropractors' practice incomes below what it would be if insurance reimbursements were fairly and equitably determined by Trigon.

Additionally, it is clear that under the new paradigm, referrals to chiropractors fiom medical doctors would increase, probably substantially: The concerted action of Trigon and the organizations of medical doctors prevents, or at least

seriously limits, such referrals, resulting in further, large economic harm to chiropractors.

Patients and their families are harmed to the extent that an often preferred and proven source of care is made more expensive to them and thus to some degree denied them. Patients either must pay more for chiropractic than they otherwise would if it were insurance-covered, or shift to a lower out-of-pocket-cost provider, risking poorer outcomes. This loss also extends to time lost from work, with the resulting reduced family income. Accordingly, patients incur some or all of the following impacts: higher out-of-pocket costs, treatment by types of providers not their first choice, possibly poorer treatment results, larger income losses from work absence, additional costs on family members for providing care during extended work absences of the primary wage earners, and other impacts, psychological and social.

Further, the use of less effective and more expensive treatments for back pain raises the costs of insurance for everyone, including the families or individuals who purchase their insurance themselves.

Employers are hurt in two ways: First, they represent the largest purchasers of health insurance, and the higher insurance costs resulting from bias in favor of medical, surgical, and hospital care relative to chiropractic care are largely paid for by employers who provide group health insurance plans. Additionally, the proven superior efficacy in terms of functional mobility of chiropractic treatment of back injuries means that workers denied such care will impose on their employers higher Workers Compensation costs and greater productivity losses from work absences. (AHCPR, citing a 1986 study, states: "Moreover, although medical costs are high,

loss of time from work as well as the disability payments for work-related low back problems can together cost up to three times as much as medical treatment.")[12]

Ultimately, society as a whole is the loser in respect to health care costs, personal disability, and productivity losses when all proven treatments are not equally available. Economic and social efficiency – both cost and quality – in the provision of care is sacrificed when the best modality for each patient and procedure is not on the menu of choice. We thus fall short of the essential goal of a free market economy, "value for money."

Accordingly, it is my conclusion that Trigon and the medical doctors of Virginia acting through their various medical organizations, have acted in combination to place restraints on chiropractors' competitive position in providing treatment for back pain and injury, and that immediate removal of these restraints would be in the best interests of patients, the households-businesses, and governments that pay for health insurance, businesses that suffer financial and productivity losses when workers are injured, the chiropractic profession, and thus virtually all of society.

IV. ESTIMATED FINANCIAL DAMAGES TO PLAINTIFF CHIROPRACTORS FROM RESTRAINTS ON COMPETITION BY TRIGON AND VIRGINIA MEDICAL PHYSICIANS

The calculable damages to chiropractors in Virginia, including the plaintiffs in this case, result from Trigon's actions to (A) employ discounting and leveling to reduce payments to chiropractors below levels paid to medical doctors for the same services and (B) reduce the demand for chiropractic services below what this demand would be if the "new

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[12] Stembach, RA. Survey of pain in the United States: The Nuprin pain report. Clin J Pain 1986;2(l):49-53, cf. AHCPR, op. cit, p. 3.

paradigm" implied in the AHCPR Guidelines[13] were followed by medical doctors.

To arrive at a dollar measure of the harmful impact of Trigon's actions on the chiropractors who are the plaintiffs in this case, Trigon's impact on all Virginia chiropractors first is shown, and the plaintiffs share of this adverse effect is derived.

Trigon Has Reduced Its Payments To Chiropractors In Three Ways.

< Trigon has imposed unreasonably low limitations or "caps" on insured persons for chiropractic services.

< Trigon has reduced payments to chiropractors for the same services performed by medical doctors by compensating chiropractors first at 70% and subsequently only 60% of the reimbursement rates to medical doctors.

< Trigon has used leveling to further reduce payments for certain types of procedures performed by chiropractors.

The effects of each such tactic will be evaluated, and then this analysis will turn to evaluating the effects on chiropractors of Trigon's policy of restraining the demand for chiropractic services by deterring patient referrals by medical doctors to chiropractors.

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13 Previously cited.

A. Trigon's Reduced Payments to Chiropractors

1. Caps.

The annual ceiling or cap on chiropractic benefits for Trigon insured patients, which limits to $500 the amount Trigon will pay for any patient's chiropractic treatments within a year, causes patients to either stop their chiropractic treatment when the cap is approached or forego chiropractic treatment entirely. While the extent to which caps reduce patients' patronage of chiropractic is not known, Trigon puts the number of insured who exceed the chiropractic cap at 21,192 for 1996-2001. If only some of these Trigon insured patients stopped their chiropractic treatment because the insurance ceiling had been reached, the financial loss to Virginia chiropractors would be significant. The high incidence of back injuries among the total population suggests that any factor limiting treatment may affect a large number of potential chiropractic patients, if not a high percentage of the population.

2. Reducing payments to chiropractors for services identical to those of medical doctors.

Of all payments to Virginia chiropractors, about 35% are for non-CMT code procedures and 65% are for CMT code procedures.[14] As noted, for these non-CMT code procedures, payments to chiropractors were discounted by 30% up to November, 1996, and by 40% after then. In other words, chiropractors, for the same services as also performed by medical doctors, were paid at 70% of the medical doctors' rate until November 1996 and at 60% of the medical doctors' rate since then.

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14 ACA financial analysis of money lost by chiropractors.

If this arbitrary and discriminatory 30-40% reduction in payments to chiropractors were not in place and Trigon had compensated Virginia chiropractors at the same rates as medical doctors, for the years 1996-2001 Trigon payments would have been $20,051,732 greater than they actually were, as shown in Table 1. The Actual Payments listed in the second column of Table 1 were taken from the "ACA financial analysis of money lost by chiropractors," which relied on the data in Trigon Document TR20020001.

Table 1
Trigon-Imposed Underpayment for
Non-CMT Code Services to All Virginia Chiropractors
1996-2001

Year	Actual Payments to Virginia Chiropractors for Non-CMT Code Services	Adjustment Factor	Payments But For Trigon-Imposed Reduction
2001	57,528,676	(x 1.66)	$12,497,602
2000	6,148,179	»	10,205,997
1999	4,915,779		8,160,193
1998	4,601,106		7,637,836
1997	4,364,450	"	7,244,987
1996	4,333,272	(x 1.43)	6,196,579
TOTAL	$31,891,462		$51,943,194

TRIGON-IMPOSED UNDERPAYMENT FOR NON-CMT CODE SERVICES TO ALL VIRGINIA CHIROPRACTORS, 1996-2001: $51,943,194 - $31,891.462 = $20,051.732.

For CMT code procedures, which represent the other two-thirds of Trigon payments to chiropractors, Trigon has reduced payments by leveling reimbursements for code levels 98940, 98941, and 98942. This has been done, as noted, by using

the lowest Relative Value number, that for code 98940, to calculate the reimbursement rates for all three codes. In this manner, Trigon underpays for all CMT procedures except the lowest-reimbursement procedure. This underpayment per code procedure is shown in Table 2.

Table 2
Trigon Underpayment per Procedure Resulting from Leveling

CMT CODE	Appropriate Reimbursement Rate*	Trigon Leveled Reimbursement Rate[15]	Trigon Under-payment per Procedure
98940	$31.25	$31.25	$0
98941	43.13	31.25	11.88
98942	55.90	31.25	24.65

*Calculated by multiplying RBRVS RVU by the prevailing dollar conversion factor.

These Trigon underpayments per procedure, multiplied by the number of procedures in each code compensated by Trigon in the years 1996-2001, establish the amount by which chiropractors were undercompensated due to leveling. This calculation occurs in Table 3, which shows the underpayment to amount to $15,398,843.

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15 PPO reimbursement rate July 1998 and later. Trigon's PAR (17% of Trigon members) rate is higher and the HMO rate (19% of Trigon members) is, to the extent known from plaintiffs' records, lower.

Table 3
Total Number of CMT Code Procedures Performed By Virginia Chiropractors Paid By Trigon, 1996-2001

Code	Number of procedures	Trigon underpayment factor	Amount underpaid
98940	1,088,614[16]	SO	$0
98941	1,032,888[17]	11.88	12,270,709
98942	126,902[18]	24.65	3,128,134

TOTAL UNDERPAYMENT FOR ALL CMT CODES: 1996-2001
$15,398,843

Accordingly, thus far in the damages analysis, the cumulative monetary impacts of Trigon's large percentage reductions to chiropractors for non-CMT code treatments and the leveling of CMT code treatments for 1996-2001 amount to ($20,051,732 plus $15,398,843), $35,450,575.

B. Trigon's Re-Writing of AHCPR Clinical Practice Guidelines for Low Back Pain: Deterring the Demand for Chiropractic by Failure to Encourage Referrals by Doctors of Medicine to Doctors of Chiropractic.

The loss in income for chiropractors because Trigon reformulated the AHCPR guidelines to minimize referrals from MDs to DCs that would have occurred under the new

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16 Trigon PAR/PPO Data

17 Trigon PAR/PPO Data

18 Trigon PAR/PPO Data

paradigm of treatment for back pain is not precisely calculable, but an educated estimate using the best available data can be made.

The following data provide the background for rendering these educated estimates:

US and Virginia Population Data:[19]

2002 US population: 281.4 million.

2002 Virginia population: 7.1 million.

Current Virginia population 18 years and over: 5,340,253.

Trigon Coverage in Virginia

34% of Virginia population, about 2,414,000 persons, are covered by Trigon health insurance.

Therefore, it is estimated that 34% of the Virginia population, 1,815,686 persons, in the 18 and over age group are covered by Trigon.

The Incidence of Back Pain and its Treatment

In recent years, on average, 9.4% of the national population sought treatment from chiropractors[20]

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19 Bureau of the Census, U.S. Department of Commerce.

20 This percentage is the arithmetic average of the percent of the population seeking chiropractic care in 1990, 1993, and 1997. See Eisenberg, JAMA (1998, Vol.280, pp.1569-75) and Eisenberg, NEJM (1993; 328(4): 246-52.

Of those seeking chiropractic treatment, 45% do so for back pain.[21]

Therefore, on average, at least 4.23% (45% of 9.4%) of the Virginia population 18 years and older can be assumed to comprise the potential demand for chiropractic treatment of back pain each year.

1. The Potential and Actual Usage of Chiropractic for Back Pain Among Trigon Insured

This average rate of use of chiropractic in treating back pain, 4.23%, and the size of the subgroup (the 18 and older Trigon-insured) together tell us the potential annual demand for chiropractic treatment of back pain in Virginia. That demand is calculated as ranging from 72,543 in 1996 to an estimated 78,242 in 2001. In the same time frame, the actual number of Trigon insured in this age category who actually sought such treatment ranged from 26,275 in 1996 to 74,477 in 2001, far fewer each year than the corresponding potential demands. These calculations and comparisons appear in Table 4.

Table 4 Potential Demand and Actual Demand for Chiropractic Treatment of Back Pain by Trigon Insured Virginia Population 18 Years of Age and Older, 1996-2001

Year	Population 18 and Over •	Potential Demand (4.23% of Population)	Actual Demand (TRIGON Insured Treated)
2001	1,849,686*	78,242	74,477

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21 Shekelle, P.G., Adams, A.H., Chassin, M.R., Hurwitz, E.L. Park, R.E., Phillips, R.B., and Brook, R.H. The Appropriateness of Spinal Manipulation of Low Back Pain: Indications and Ratings by a Multidisciplinary Expert Panel, Santa Monica, Calif.: RAND, R-4025/2-CCR/FCER, 1991.

2000	1,815,686**	76,804	63,385
1999	1,770,755***	74,903	50,735
1998	1,747,229	73,908	42,414
1997	1,733,412	73,323	34,814
1996	1,714,965	72,543	26,275

*Estimated
**Calculation
***Census

The deterred demand, the shortfall in chiropractic patients due to Trigon's and its medical physician panel's largely successful efforts to block referrals from medical doctors to chiropractors, is highlighted in Table 5, which shows these annual differences between potential and actual patients enumerated in Table 4.

Table 5 Deterred Demand for Chiropractic Treatment of Back Pain by Trigon Insured 18 Years and Older 1996-2000

Year	Deterred Demand (Potential less Actual)
2001	3,765
2000	13,419
1999	24,168
1998	31,494
1997	38,509
1996	46,268

To establish the lost income to Virginia chiropractors from Trigon's and its medical physician panel's non-referral strategy, the number of deterred cases each year is

multiplied by the average Trigon cost per case, with adjustments made for the percentage reduction of 40% for non-CMT code treatments and the leveling of payments for CMT code treatments.

Previous calculations show Trigon underpayments to chiropractors in the period 1996-2001 for both non-CMT and CMT code treatments to have totaled 535,450,575. In this same period Trigon paid chiropractic claims on behalf of 292,102 claimants. Accordingly, the average underpayment per chiropractic claimant per year is $121.36. Adding this to the average actually paid by Trigon per claimant of $294.14[22], we arrive at $415.50 as the per patient income per year that chiropractors would have received if the percentage reductions for non CMT services and-the leveling of CMT services had not occurred.

In Table 6 chiropractors' total lost income is determined by multiplying for each year the deterred demand and-the undiminished average annual per patient chiropractic expenditure of $415.50. The total lost income from this deterred demand for the period comes to $65,492,356.

Table 6 Virginia Chiropractors' Lost Income From Trigon Induced Deterred Demand, 1996-2001 (Deterred Demand x $415.50)

	Deterred Demand (Patients)	Lost Income
2001	3,765	1,564,357
2000	13,419	5,575,594
1999	24,168	10,041,804
1998	31,494	13,085,757
1997	38,509	16,000,490

22 1997-2001 average.

1996	46,268	19,224,354
TOTAL	157,623	65,492,356

To this point three losses of income to chiropractors have been identified. These losses, and the measured magnitude of each, are:

Losses from annual caps on patient chiropractic benefits: unspecified but possibly large.

Losses from underpayments caused by discounting non-CMT code treatments and leveling CMT code treatments: $35,450,575.

Losses from deterred demand: $65,492,356.

Total calculable losses to Virginia chiropractors, 1996-2001: $100,942,931.

The next task is to determine the share of the plaintiffs in this action of these total losses to all Virginia chiropractors. This is accomplished by calculating plaintiffs' share of all chiropractor payments made by Trigon, and using this ratio to determine their share of Trigon-caused total lost chiropractor income.

Between 1997 and 2001[23], plaintiffs received a grand total of $1,814,593 in Trigon payments for chiropractic services. In the same period, Trigon paid out $576,251,581 to all Virginia chiropractors. Hence, plaintiff chiropractors received 2.38% of total Trigon payments, and can be assumed to have suffered a

---

[23] Data showing Trigon payments to these providers for 1996 were not available.

comparable percentage loss in the total Virginia picture. Using the 2.38% figure, the plaintiffs' combined share of that total loss is $2,402,442.[24]

The last step in this analysis is to apportion this lost income among the individual plaintiffs. This is accomplished in Table 7, where each plaintiffs respective dollar loss is calculated; These losses are seen to range from a low of $7,448 to a high of $540,429.

Table 7 Plaintiff Chiropractors' Share of Calculable Monetary Damages Caused by Trigon 1996-2001		
Chiropractor	Share of Plaintiffs' Total Damages (Percent)	Share of Plaintiffs' Total Damages (Dollars)
Douglas F. Ambrose	1,235	29,670
George W. Chirkinian	6,908	165,961
Douglas M. Cox	18,231	437,989
George B. McClelland	6,097	146,477
James M. Porter	1,.310	7,448
Larry L. Stine	22,495	540,429
William R. Thesier	14,651	351,982
John.C. Willis	11,922	286,419
Jerry R. Willis	13,247	318,251
Wendy Holden Willis	2,020	48,529
Steven W. Yates	2,885	69,310

[24] This figure differs slightly from the total in Table 7 due to rounding.

TOTAL	100.000%	2,402,465

Conclusion Regarding Damages to Individual Plaintiffs

The above data strongly support the view that damages to individual plaintiff chiropractors from Trigon's exclusionary actions in the period 1996-2001 were substantial, and would not have been incurred except for the strategies employed by Trigon in agreement with the medical doctors of Virginia acting through representatives of the medical organizations to which they belong.

Dated: March 7,2003

/s/ Leonard G. Schifrin
Leonard G. Schifrin, Ph.D

Appendix A

Publications Sent by Foundation for Chiropractic Education and Research in Response to Request for "Best Studies on Chiropractic Cost and Effectiveness" Published in the 1990s"

1. The State of Chiropractic Research. Meeker, Mootz, and Haldeman. Top Clin Chiropr 2002; 9(1): 1-13

2. Conservative Treatment of Acute and Chronic Nonspecific Low Back Pain. Van Tulder, Koes, and Bouuter. SPINEVolume22, Number 18, pp 2128-2156,1997.

3. Spinal Manipulation vs. Amitriptyline for the Treatment of Chronic Tension-type Headaches: A Randomized Clinical Trial. Boline, Kassak, et al. Journal of Manipulative and Physiological Therapeutics, Volume 18 Number 3 March/April 1995.

4. The Effect of Spinal Manipulation in the Treatment of Cervicogenic Headache. Nilsson, Christrensen, and Harrington. Journal of Manipulative and Physiological Therapeutics, Volume 20 Number 5, June 1997.

5. A Critical Analysis of Randomised Clinical Trials on Neck Pain and Treatment Efficacy.A Review of the Literature. Kjellman, Skargen, and Oberg. Scand J Rehab Med 31; 139-152,1999.

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8. Single-blind randomised controlled trial of chemonucleolysis and manipulation in the treatment of symptomatic lumbar disc hemiation. Burton, Tillotson, and Cleary. Eur Spine J (2002) 9: 202-207.

9. A Symptomatic Classification of Whiplash Injury and Implications for the Treatment. IChan, Cook, et al. The Journal of Orthopaedic Medicine 21 [1] 1999.

10. Cost Comparison of Chiropractic and Medical Treatment of Common Musculoskektal Disorders: A Review of the Literature after 1980. Branson. Top Clin Chiro 1999; 6(2): 57-68.

CURRICULUM VITAE

PERSONAL INFORMATION

1. Name: Leonard G. Schifrin Date: January 12, 1999
Home Address: 163 DevonRoad, Williamsburg, VA 23188-1542
Phone:(757)565-3191

2. Academic degrees, institutions, dates
Ph.D. in Economics, University of Michigan, 1964 M.A. in Economics, University of Texas at Austin, 1958 B.A. in Economics, University of Texas at Austin, 1954

ACADEMIC POSITIONS

3. Current:
Professor of Economics, Emeritus College of William & Mary Williamsburg, Virginia

4. Immediately Prior to Retirement:
Chancellor Professor of Economics
College of William and Mary
Williamsburg, Virginia

Faculty Fellow
Eastern Virginia Center for Mental Health Studies
1984-present

5. Other:
University of Bristol
Bristol, England
19 1993-1994

Visiting Professor of Health Economics
Department of Epidemiology and Public Health Medicine

Medical College of Virginia
Richmond, Virginia
1982-1992

Clinical Professor of Preventive Medicine
Department of Community Medicine

University of Adelaide
Adelaide, South Australia
1988

Visiting Professor of Economics
Department of Economics and MBA Program

University of Bristol
Bristol, England
1984

Visiting Professor of Health Economics
Department of Epidemiology and Community Medicine

Stanford University
Stanford, California
1975-76 1975-1976

Visiting Scholar
Department of Family, Community, and Preventive Medicine
Stanford University Medical School

Yale University
New Haven, Connecticut
1962-65
Assistant Professor of Economics

University of Michigan
Ann Arbor, Michigan
1961-62
Instructor in Economics

6. Editorial positions on scholarly journals:
Board of Editors, INDUSTRIAL ORGANIZATION REVIEW .
Advisory Board, ANTITRUST LAW AND ECONOMICS REVIEW
Editorial Board,. JOURNAL OF RESEARCH IN PHARMACEUTICAL ECONOMICS

Secretary/Treasurer, Industrial Organization Society

7. Representative publications in health care economics and policy:

"Teaching Health Economics in Medical School: Experiences and Observations From the U.S.," JOURNAL OF MANAGEMENT IN MEDICINE, Vol. 3,1989-90.

"Research in Medical Economics: Patchwork Approach or Systematic Plan?,"JOURNAL OF MANAGEMENT IN MEDICINE, Vol.3, 1988-89.

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An Examination of Alternative Proposals for Improving Public Health Care Services in James City County (with others). Thomas Jefferson Program in Public Policy, College of William and Mary. Williamsburg, VA, 1992.

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Diagnostic Ultrasound Imaging in Pregnancy. Office of Applications of Medical Research, National Institutes of Health, Bethesda, Md., 1984. Washington, D.C, 1969.

The Drug Makers (Contributor and Consultant), Task Force on Prescription Drugs, Department of Health, Education and Welfare, Washington, D.C, 1968.

ARTICLES IN NON-REFEREED CONFERENCE PROCEEDINGS (INCLUDING U.S. CONGRESSIONAL HEARINGS):

"The Health Care Cost "Problem"', QUARTERLY REVIEW OF ECONOMICS AND BUSINESS, Winter, 1990.

"The Societal Impacts of Motor Vehicle Accidents When Alcohol is a Factor, and Some Economic Facets of Beverage Alcohol Production and Consumption," OVERSIGHT INTO THE ADMINISTRATION OF STATE AND LOCAL COURT ADJUDICATION OF DRIVING WHILE INTOXICATED, Hearings, Subcommittee on Courts, Senate Committee on the Judiciary, U.S. Government Printing Office, Washington, D.C, 1982.

"The Promotion and Use of Psychotropic Drugs," ABUSE OF DANGEROUS LICIT AND ILLICIT DRUGS–PSYCHOTROPICS, PHENCYCLFDINE (PCP) 'AND TALWIN. Select Committee on Narcotics Abuse and Control, House of

Representatives, Hearings, U.S. Government Printing Office, Washington, D.C, 1979.

"Economics of Regulation of Prescription Drag Prices," Proceedings of the Seminar on the Economics of the Pharmaceutical Industry, INTERNATIONAL JOURNAL OF MANAGERIAL ECONOMICS, 1979. Reprinted in ISSUES IN PHARMACEUTICAL ECONOMICS, Robert Chien, ed., Lexington Books, D.C. Heath and Co., 1979.

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"Poverty and .Health Care: An Economic Perspective," HEALTH CARE FOR THE POOR. Donnie J. Self, ed., Eastern Virginia Medical School, Norfolk, Va., 1976. Reprinted in SOCIAL ISSUES IN HEALTH CARE, Donnie J. Self, ed., Teagle and Little, 1977.

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INVITED SCHOLARLY PAPERS AND TALKS:

"Three Perspectives on the Needs and Capabilities of Public Health in Virginia". Fifth Congress, Associated Schools of Public Health in the European Region, Bielefeld, Germany, November 30-December 2,1993.

"Public Policy Toward Biotechnology: Balancing Promotion and Regulation," Conference on Biotechnology: Future Directions, Future Policies. College of William and Mary, March 29-31, 1990.

"A Doctor Surplus," The William and Marv Alumni Gazette. July/August 1983. Reprinted in Virginia Hospital Association Perspective. Vol. 1, No. 2, September 23, 1983.

"Cost Effectiveness of Prescription Drugs," Discussant, Project HOPE, Millwood, Va., July 1982

"The Drug Lag: A Prescription for Public Policy," Ohio Pharmaceutical Seminar, Ohio State University, March 29,1982.

"Can Health Care Costs be Controlled?." University Lecture Series, Williams College, Williamstown, Mass., April 1982.

"Societal Costs of Alcohol Abuse in the United States," Conference on the Economic Aspects of Alcohol Use and Abuse. Wivenhoe Park Conference Center, University of Essex, Colchester, England, November 12-15, 1982.

"Health Outcome Measures: Implications for Drug R & D," Foresight Seminars on Pharmaceutical Research and Development. U.S. House of Representatives. Institute for Alternative Futures, March IS, 1980.

"Influencing Health Care Delivery Through Health Care Financing: Comparing and Contrasting Proposals for National

Health Insurance," University of Virginia School of Medicine, (Health Services Research Program), 1977,1979.

"Economic Issues in Health Care Delivery," University of Virginia School of Medicine, (Health Services Research Program), 1977,1978, 1979.

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"Social Justice in the Access to Health Care Delivery," National Council of Churches of Christ Conference on Distributive Justice in Health Care, Charleston, South Carolina, 1977.

"Health Care Delivery and Health Care Financing," Children's Memorial Hospital, Northwestern University, Chicago, Illinois, (Grand Rounds), 1977.

"Financing Health Care," Eastern Virginia School of Medicine, (Medicine and Society Forum), 1977.

"Pricing, Profits and Public Policy in the Drug Industry," Ohio State University School of Pharmacy, (Ohio Pharmaceutical Seminar), 1977.

"Economic Issues in Health Care," University of Michigan, (Department of Economics), 1977.

"The Drug Industry: An Economic Perspective," Stanford University Department of Economics, (Course: Economics of Health Care), 1976. ' "The Development, Manufacture, and Promotion of Ethical Drugs," Stanford University School of Medicine, (Course: Pharmacology IT), 1976.

"The FDA, Drug Regulation and the Drug Lag Issue," Stanford University School of Medicine, (Pharmacology Department Seminar), 1976.

"Cost Benefit Analysis in Health Care," Stanford University School of Medicine, (Clinical Scholars Seminar), 1976.

"The Economics of Health Care," Eastern Virginia Medical School, (Behavioral Sciences Section), 1976. "Poverty and Health' Care," Eastern Virginia Medical School, (Behavioral Sciences Section), 1976.

"Economic Policy Toward the Ethical Drug Industry," Ohio State University School of Pharmacy, (Graduate Seminar in Pharmacy Administration), 1976.

"The Economics of Prescription Drugs," Stanford University, School of Medicine, (Course: Medicine and Society), 1975.

Discussant, "True Rates of Return on Pharmaceutical Investment," American University, Second Conference on Innovation in the Pharmaceutical Industry, 1974.

"Compulsory Licensing of Ethical Drug Product Patents," American UniversitySeminar on the Economics of Innovation in the Pharmaceutical Industry, 1969.

"Pharmaceutical Research and Economic Implications," City University of New York, (Seminar in Health Economics), 1969.

CONGRESSIONAL TESTIMONY.

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Subcommittee on Monopoly, Senate Select Committee on Small Business, Hearings on Competitive Problems in the Drag Industry, March 14, 1973. Subcommittee on Monopoly, Senate Select Committee on Small Business, Hearings on Competitive Problems in the Drug Industry, Jan. 19, 1968

LITIGATION CONSULTATION AND TESTIMONY:

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U.S. Dept. of Justice v. Pfizer Corp. et. al. Sec. 1 and 2 Sherman Act case against tetracycline manufacturers.

Expert witness for U.S. Department of Justice, Antitrust Division. U.S. Dept. of Justice v. Ciba-Geigy Corp. Sec. 2 Sherman Act case regarding licensing of hydrochlorothiazide.

Expert witness for U.S.Department of Justice, Patent Division. Ampicillin Antitrust Litigation D.D.C. Misc. 45-70 Sec. 2 Sherman Act case regarding restrictive licensing of ampicillin by Bristol-Myers Corp. Expert witness for plaintiff states, cities, et. al. in class action.

Pfizer Corp. v. International Rectifier Corp. Doxycycline patent infringement damages case. Expert witness for defendant.

Johnson v. HEW Suit under Freedom of Information Act for availability of evidence on adverse drug reactions during testing. Expert witness for plaintiff.

Personal injury cases related to drug Oraflex (Lilly brand of benoxaprofen).Expert witness for plaintiffs.

Jack Eckerd Corporation v. Merck & Co. Sec. 2 Sherman Act case relating to vertical distribution of Merck drug products. Expert witness for plaintiff.

Hybritech, Inc. v. Abbott Laboratories Sherman Act case regarding monopolization in biotechnology industry, immunodiagnostics markets. Expert witness for plaintiffs.

Personal Injury cases related to drug Feldene (Pfizer brand of piroxicam). Expert witness for plaintiffs.

Ballard Medical Products v. Smiths Industries Medical Systems. Patent infringement and monopolization case relating to closed-system respiratory suction catheters. Expert witness for Ballard Medical Products.

Current: Litigation regarding Virginia MEDICAID' reimbursement payments to HCMF Corporation of Virginia Expert witness for plaintiffs HCMF

Numerous pharmaceutical product liability cases regarding use of "phen-fen" drug combination. Expert witness for plaintiffs

GOVERNMENT:

Consultant, Senate Labor and Human Resources Committee, 1990. Consultant, Senate Special Committee on Aging, 1990

Consultant, Antitrust Division, Department of Justice, 1973-1979.

Member, Pharmaceutical Review Advisory Committee, Department of Health, Education and Welfare, 1977-1978.

Consultant, Patent Division, Department of Justice, 1975.

Consultant, Bureau of Competition, U.S. Federal Trade Commission, 1973-1974
Consultant, Office of Research and Statistics, Social Security Administration, 1968-1973. Consultant, Tax Division, Department of Justice, 1968-1969.

Consultant, Subcommittee on Monopoly (Nelson Committee), Senate Select Committee on Small Business, 1966-1968.

Consultant, Task Force on Prescription Drugs, Office of the Secretary of Health, Education and Welfare, 1967-1968.

No. 04-312

Supreme Court, U.S.
FILED
OCT 6 - 2004
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In The Supreme Court of the United States

AMERICAN CHIROPRACTIC ASSOCIATION, INCORPORATED, a non-profit corporation, *et al.*,

Petitioners,

v.

TRIGON HEALTHCARE, INCORPORATED, *et al.*,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

E. Duncan Getchell, Jr.*
Howard Feller
Bryan A. Fratkin
McGUIREWOODS LLP
One James Center
901 East Cary Street
Richmond, Virginia 23219
(804) 775-1000

Counsel for Respondents
Counsel of Record

LANTAGNE LEGAL PRINTING
801 East Main Street Suite 100 Richmond, Virginia 23219 (800) 847-0477

QUESTIONS PRESENTED

The Questions Presented need to be restated because they contain misstatements of the facts and issues presented to the Courts below.

First, in their Questions Presented and throughout their Petition, the Petitioners claim that Trigon's decisions as an insurance company were connected to the boycott of chiropractors by the medical doctor members of the American Medical Association, which ended in 1980.[1] Petition at i, 2-3, 6. However, as the Fourth Circuit found, there is absolutely no evidence that Trigon's policies were related in any way to the American Medical Association's boycott of chiropractors. App. 6a ("Although Trigon is a licensee of Blue Cross & Blue Shield of America, there is no record evidence connecting Trigon to this boycott.").[2]

Second, the Petitioners suggest that, in addition to the alleged conspiracy between Trigon and the medical doctors who served on its Managed Care Advisory Panel, there was a conspiracy between "a health insurance company [Trigon] and its medical doctor employees." Petition at i. Yet, the record is clear that the Petitioners made no such claim below.

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[1] *See Wilk v. Am. Med. Ass'n*, 895 F.2d 352, 356, 374 (7th Cir. 1990).

[2] The Fourth Circuit's opinion is reported at *American Chiropractic Ass'n v. Trigon Healthcare, Inc.*, 367 F.3d 212 (4th Cir. 2004).

App. 13a ("American Chiropractic did not argue that Trigon conspired with its own employees serving on the MCAP."). Moreover, any claim that Trigon conspired with its own employees clearly would be barred by the intracorporate immunity doctrine. *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 769 (1984).

The two Questions Presented should be more appropriately combined into one and restated as follows:

> Did the Fourth Circuit correctly hold that Trigon and a number of medical doctors, who were appointed by their medical associations to serve on a committee created by Trigon to provide advice on clinical issues related to Trigon's managed care plans, had a unity of interest such that they were legally incapable of conspiring under the intracorporate immunity doctrine?

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

Respondents Trigon Healthcare, Inc., Trigon Insurance Co., and Trigon Health and Life Insurance Company are all 100% wholly-owned subsidiaries of Anthem, Inc., which is a publicly traded corporation. No other publicly held corporation owns 10% or more of Anthem, Inc.'s stock. Respondent Trigon Administrators, Inc. was previously a wholly-owned subsidiary of Trigon Healthcare, Inc., but has since been sold to CompManagement, Inc., which is not a publicly traded corporation and is not affiliated with Anthem, Inc. Mid-South Insurance Company was previously a wholly-owned subsidiary of Trigon Healthcare, Inc., but has since been sold to World Insurance Company, which is not a publicly traded corporation and is not affiliated with Anthem, Inc. Although Petitioners identify Anthem, Inc. as one of the Defendants-Appellees in their Petition at vi, Anthem, Inc. was never named as a Defendant and was not an Appellee in the proceedings below.

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STATEMENT OF THE CASE

Trigon is compelled to submit the following Statement of the Case to correct the misstatements of facts contained in the Petitioners' Statement of the Case and Background of the Case.

In August 2000, two chiropractic associations, individual chiropractors and a number of patients (collectively, "Petitioners"), sued Trigon Healthcare, Inc. and several of its subsidiaries (collectively, "Trigon") and the National Blue Cross and Blue Shield Association[3] in an eight-count Complaint, alleging an antitrust conspiracy in violation of the Sherman Act (15 U.S.C. § 1), unlawful monopolization, a RICO violation, a state law conspiracy, a state insurance law violation, tortious interference and breach of contract. After full discovery, the United States District Court for the Western District of Virginia, Abingdon Division, granted Trigon's summary judgment motion on the antitrust conspiracy claim and all of the other remaining claims that previously had not been dismissed. App. 43a-58a.[4]

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[3] The Petitioners voluntarily dismissed the National Blue Cross and Blue Shield Association as a defendant early in the case.

[4] The District Court's opinion is reported at *American Chiropractic Ass'n v. Trigon Healthcare, Inc.*, 258 F. Supp. 2d 461 (W.D. Va. 2003).

The undisputed facts in the record established that Trigon's business, as a for-profit health insurance company, consists of providing medical coverage to its members in accordance with the terms of the relevant health plans and making a network of healthcare providers, including medical doctors, hospitals, pharmacies, chiropractors, and therapists, available through which those members can obtain medical services. App. 4a. Trigon creates this network of healthcare providers by entering into contracts with providers who are willing to abide by Trigon's terms and conditions, as set forth in Trigon's provider agreements. *Id.* Trigon attempts to control and limit its costs so that it can price its insurance products competitively. *See id.*; *see also* App. 51a-52a. Since Trigon's largest cost category is its payments to providers, Trigon's economic incentive is to pay providers, including chiropractors, at the lowest possible price that will enable it to maintain an adequate network to provide access and covered services to its members. *Id.*

Trigon has provided coverage for chiropractic services since the 1980s, and Trigon "acknowledges that chiropractic care has a health effect, a positive health effect when rendered appropriately." App. 4a-5a. During the relevant time period, the use of chiropractors by Trigon members substantially increased. App. 21a. From 1996 to 2001, the number of chiropractors participating in Trigon's networks nearly doubled. App. 5a. By entering into provider contracts with many new chiropractors, Trigon increased the supply of chiropractors available for its members, which increased both the access of its members

and the opportunities for referrals to chiropractors. *See id.* Furthermore, the number of Trigon members who obtained treatments from chiropractors nearly tripled. *Id.* In addition, Trigon's payments to chiropractors for providing treatments to Trigon's members almost doubled, from approximately $12.4 million to $21.5 million. *Id.* Finally, Trigon's payments to chiropractors as a percentage of its total payments to all healthcare providers increased by 14%, which was at the expense of medical doctors and other providers, whose share of Trigon's payments decreased. App. 51a.

Despite the substantial increase in utilization of and payments to chiropractors during the relevant time period, the Petitioners filed a claim against Trigon, alleging that Trigon intentionally harmed chiropractors and furthered the interests of medical doctors by discouraging Trigon's members from using, and by preventing referrals to, chiropractors. Specifically, the Petitioners claimed that Trigon conspired with the medical doctor members of one of its committees, the Managed Care Advisory Panel ("MCAP"), to create a low back pain guideline, entitled "Managing Low Back Problems in Adults," that allegedly de-emphasized the importance of spinal manipulation because it did not recommend spinal manipulation in place of medications for the treatment of back pain and did not include a definition of manipulation as the type given by

chiropractors.[5]

The evidence, however, was undisputed that Trigon and the MCAP members had a unity of interest, and also had not entered into a conspiracy to harm chiropractors. The MCAP was formed by Trigon and chaired by a Trigon officer. App. 10a. The members consisted of six Trigon employees and nine medical doctor representatives of various professional associations who were appointed to serve on this committee. *Id.* The MCAP had no decision-making authority and had no ability to control Trigon's decisions. *Id.* Rather, its function was limited to providing input, advice and expertise on clinical issues relating to Trigon's managed care plans, such as quality control initiatives. *Id.* The MCAP medical doctor members also were never given any information regarding Trigon's specific payment policies for any providers. *Id.* As the District Court indicated, "[o]f course, there is no evidence in the record that Trigon ever discussed with the Medical Society of Virginia, or any other professional association, any policies harmful to chiropractic providers." App. 55a.

Furthermore, the Petitioners never presented any evidence to show that any referrals to chiropractors actually

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[5] The Petitioners pursued several other conspiracy theories against Trigon, and the District Court also granted Trigon's summary judgment motion as to these claims, which the Fourth Circuit affirmed. The Petitioners have not appealed the rulings on these other conspiracy claims.

were prevented, or that any patients were shifted to medical doctors, after Trigon's guideline was published. App. 53a. In fact, as both Courts below explained, the undisputed evidence established that there was no effort by Trigon to harm chiropractors and that Trigon had no economic incentive to prevent referrals to chiropractors. App. 22a, 51a-52a.

The evidence was also undisputed that Trigon's low back pain guideline was drafted solely by Trigon's employees, not by the MCAP, and was based on the 1994 federal AHCPR guideline. App. 11a, 52a. No changes were made to the text of Trigon's guideline after the MCAP reviewed it, and Trigon's employees made the final decision regarding the content of the guideline. App. 12a, 17a-18a. Significantly, the guideline did not have any relation to Trigon's coverage and reimbursement policies. App. 10a.[6]

Based on these undisputed facts, the District Court found that Trigon was entitled to summary judgment. Relying on *Copperweld Corp. v. Independence Tube Corp.*,

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[6] The Petitioners argue that Trigon's low back pain guideline was an "insurance-reimbursement guideline[], which created industry standards affecting reimbursement." Pet. at 2. This claim is a misstatement of the facts. The uncontroverted evidence was that the guideline had no relation to Trigon's payment policies for chiropractors. App. 10a. In addition, there was no evidence that Trigon's guideline became an industry standard.

467 U.S. 752, 769 (1984), the District Court applied the doctrine of intracorporate immunity and held that a "corporation cannot conspire with its employees or agents because 'the officers of a single firm are not separate economic actors pursuing separate economic interests, so agreements among them do not suddenly bring together economic power that was previously pursuing divergent goals.'" App. 47a.

The District Court then considered whether the independent personal stake exception to the intracorporate immunity doctrine applied and found that the Petitioners failed to present "any evidence to show that any of the Trigon panel members competed with them for the treatment of neuromusculoskeletal disorders." App. 49a.

As to the allegation that Trigon conspired with the professional organizations that had representatives on the MCAP, the District Court evaluated the conspiracy claim on the merits and held that "the record demonstrates that no conspiracy existed." App. 50a. The District Court stated that the Petitioners failed to adduce any direct evidence of a conspiracy, and the circumstantial evidence presented by Petitioners failed "to exclude the possibility of independent action by the [defendants]." App. 50a-51a (citing *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 768 (1984) & *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986)).

Finally, the District Court explicitly held that

Trigon's adoption of the low back pain guideline in 1996 was not proof of the existence of a conspiracy. According to the District Court,

> [t]his guideline, entitled "Managing Low Back Problems in Adults," was drafted by Trigon employees and considered (but not revised) by the Managed Care Advisory Panel. Trigon contends that its guideline, which was distributed to all of its providers including chiropractors, was merely a simplified version of a clinical guideline published by a federal agency in 1994. . . . The plaintiffs point to the opinion of their expert, Scott Haldeman, that the Trigon guideline is "inconsistent" and "in conflict" with the federal guideline, mainly because while the Trigon guideline recommends "manipulation" as a treatment option, it omits the federal definition of manipulation. The expert believes that the federal definition favors the type of manipulation given by chiropractors over other providers. Even assuming that this opinion is credible – and I find it very thin – it is insufficient circumstantial proof of a conspiracy. It is clear that Trigon's guideline follows the federal guideline in a highly abbreviated form. *The uncontested evidence is that since Trigon's guideline was issued in 1996, no chiropractor provider ever*

> *complained to Trigon about the omission of the definition of manipulation or anything else about it. Moreover, since it was issued, use of chiropractic treatment by Trigon subscribers has substantially increased.*

App. 52a-53a (internal footnotes omitted) (emphasis added).

On appeal, the Fourth Circuit unanimously affirmed the District Court's summary judgment decision. The Fourth Circuit "agree[d] with the district court that, under the intracorporate immunity doctrine, Trigon lacked the legal capacity to conspire with the medical doctors on the MCAP." App. 16a. The correct inquiry, according to the Fourth Circuit, was "whether the medical doctors, *in their role as members of the MCAP*, share a unity of interest with Trigon that makes them corporate agents of Trigon," not whether "medical doctors and insurance companies . . ., generally speaking, share a unity of interest," as the Petitioners argued. App. 17a (emphasis added). The Fourth Circuit concluded:

> Because Trigon established the MCAP to offer input on clinical issues faced by Trigon, the individual medical doctors, in their role as members of the MCAP, shared the same interest as Trigon: addressing clinical issues in a manner that would best serve its consumers, the plan enrollees. *The MCAP is without question a corporate agent of Trigon,*

> *chaired by a Trigon employee, and we believe that the intracorporate immunity doctrine applies to its actions.* The decision to consult with doctors on the MCAP does not "represent the sudden joining of economic forces that section one is designed to deter and penalize." *Oksanen* [*v. Page Mem'l Hosp.*, 945 F.2d 696, 703 (4th Cir. 1991) (en banc)]. By creating the MCAP, Trigon did not bring together independent economic forces. Instead, Trigon had "ultimate control" over the MCAP's actions and was able to employ the MCAP to pursue its interests. In fact, we are presented with even stronger reasons for applying the doctrine here than we were in *Oksanen* because, in *Oksanen*, the peer review committee and the hospital were legally distinct entities. The MCAP is not legally distinct from Trigon.

Id. (emphasis added).

In addition, the Fourth Circuit also reviewed the merits of the conspiracy claim and concluded that the evidence presented by the Petitioners was insufficient to establish the existence of a conspiracy between Trigon and the medical associations whose representatives served on the MCAP. The Fourth Circuit stated:

> At most, the MCAP meeting shows contact between two independent economic actors, but "mere contacts and communications, or the mere opportunity to conspire, among antitrust defendants is insufficient evidence [of] an anticompetitive conspiracy." *Cooper v. Forsyth County Hosp. Auth.*, 789 F.2d 278, 281 (4th Cir. 1986). . . .
>
> . . . .
>
> . . . They have pointed to no evidence that Trigon conspired with any entity in forming its policies. *In fact, the only evidence in the record is that all of the actions in dispute were taken unilaterally by Trigon employees. In the face of Trigon's affidavits that it acted unilaterally, American Chiropractic needed more to create a genuine issue of material fact.*

App. 21a-22a (emphasis added).[7]

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[7] Petitioners claim that the Fourth Circuit ignored the documentary evidence regarding the issuance of Trigon's low back pain guideline when it held that there was insufficient evidence to prove the existence of a conspiracy. Pet. at 18. This claim is plainly incorrect and is a mischaracterization of the Fourth Circuit's decision since it expressly analyzed the documents relating to the MCAP and the guideline. App. 11a-12a.

Subsequently, the Fourth Circuit denied the Petitioners' Petition for Rehearing and Rehearing En Banc. App. 60a-61a. While the District Court and Fourth Circuit granted summary judgment to Trigon as to all of the Petitioners' claims, the Petitioners have appealed only the portion of the decision relating to the intracorporate immunity doctrine.

ARGUMENT

The Fourth Circuit unanimously affirmed the District Court's determination that Trigon was entitled to summary judgment on all claims. Its decision contained detailed findings of fact which were derived from the factual record in the summary judgment proceeding.

The Court should not grant certiorari because the Fourth Circuit based its decision on independent and dispositive grounds that the Petitioners have not appealed. In addition, the decision does not conflict with any decision of this Court or any other court of appeals and does not present any legal issue warranting this Court's review.

I. The Petition Is Not Certworthy Because The Fourth Circuit Decided The Conspiracy Claim On Independent Grounds, Which Petitioners Did Not Appeal.

Supreme Court Rule 14(1)(a) states, in part, that "[o]nly the questions set out in the Petition, or fairly included therein, will be considered by the Court." The only issue raised by the Petitioners in the Questions Presented is whether the Fourth Circuit correctly applied the intracorporate immunity doctrine. As set forth below, the Petition is not certworthy because the Petitioners did not challenge in their Questions Presented the Fourth Circuit's independent and dispositive finding on the merits that the Petitioners presented insufficient evidence to prove the

existence of a conspiracy.

All of the Questions Presented explicitly state that the Petitioners are appealing whether the Fourth Circuit incorrectly applied the intracorporate immunity doctrine, as articulated in *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752 (1984), and its progeny. Pet. at i. The District Court's decision, however, was not based solely on its holding that, under *Copperweld*, Trigon was incapable of conspiring with the independent medical doctors who were appointed as representatives of various medical associations to serve on Trigon's MCAP. Significantly, the District Court also evaluated the merits of the antitrust conspiracy claim and held that there was insufficient evidence to prove the existence of a conspiracy. As the District Court stated, "[t]he specific alleged anticompetitive conduct complained of by the plaintiffs does not support the existence of an unlawful conspiracy." App. 52a.

The Fourth Circuit unanimously affirmed both of these findings. First, the Fourth Circuit ruled that the intracorporate immunity doctrine barred the claim that Trigon and the MCAP members conspired to harm chiropractors. Second, the Fourth Circuit analyzed the conspiracy claim on the merits and held that the Petitioners presented insufficient evidence to establish the existence of a conspiracy. In fact, it concluded that "the only evidence in the record is that all of the actions in dispute were taken unilaterally by Trigon employees." App. 22a.

Accordingly, both lower courts specifically analyzed whether the Petitioners presented sufficient evidence to prove that Trigon and the medical associations, which were represented on the MCAP, engaged in an unlawful conspiracy by adopting a low back pain guideline that allegedly harmed chiropractors. Moreover, the only evidence presented by the Petitioners of the alleged conspiracy between Trigon and the medical associations consisted of the contacts and communications at the MCAP meeting. Thus, the allegation that the medical associations conspired with Trigon was based solely on the evidence relating to the conduct of the associations' representatives on the MCAP. In other words, the only way in which the medical associations were alleged to have conspired with Trigon was through the activities of their medical doctor representatives who served on the MCAP.

In deciding that this evidence was insufficient to withstand summary judgment, the Fourth Circuit found that the MCAP meeting at most showed contacts between Trigon and the independent MCAP members, "but 'mere contacts and communications, or the mere opportunity to conspire, among antitrust defendants is insufficient evidence [of] an anticompetitive conspiracy.'" App. 21a (quoting *Cooper v. Forsyth County Hosp. Auth.*, 789 F.2d 278, 281 (4th Cir. 1986)). Therefore, the Fourth Circuit determined that the MCAP meeting discussions about the guideline did not establish sufficient evidence of a conspiracy.

As a result, both the Fourth Circuit and the District

Court fully considered the merits of the antitrust conspiracy claim and found that the Petitioners failed to present sufficient evidence to prove the existence of a conspiracy. App. 21a-22a. This portion of the Fourth Circuit's decision is not challenged in the Questions Presented and thus has not been appealed.

By limiting their two Questions Presented to whether the Fourth Circuit correctly applied the intracorporate immunity doctrine, Petitioners have failed to seek this Court's review of the independent and dispositive issue of the sufficiency of the evidence to establish a conspiracy between Trigon and the medical doctors or the associations they represented. Sup. Ct. R. 14(1)(a).[8] Thus, were the Court to review the intracorporate immunity issue raised in the Petition, its decision on that issue would be merely advisory and would have no practical impact on the outcome because the Fourth Circuit also dismissed the antitrust conspiracy claim on the merits. As a result, the Petition is not certworthy and should be denied.

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[8] The question of whether the evidence was sufficient to establish the existence of a conspiracy also is not "fairly included" within the "questions set out in the Petition." Sup. Ct. R. 14(1)(a). The application of the intracorporate immunity doctrine centers on consideration of whether the parties were legally capable of conspiring, which is far different from the question of whether there is sufficient evidence, direct or circumstantial, to prove the existence of an anticompetitive conspiracy.

In addition, if Petitioners now claim that they are seeking review of the Fourth Circuit's decision on the merits of the antitrust conspiracy claim, their Petition should likewise be denied because they would be asking the Court to hold that the Fourth Circuit's factual findings were in error or that the Fourth Circuit misapplied the law to the facts. Neither of those are valid grounds for granting a petition for writ of certiorari. Sup. Ct. R. 10; *see also Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 336 U.S. 271, 275 (1949) (Court "cannot undertake to review concurrent findings of fact of two courts below in the absence of a very obvious and exceptional showing of error").

II. The Fourth Circuit's Decision Is Consistent With Legal Principles Established In *Copperweld* And *Allied Tube*.

A. The Fourth Circuit's Decision Specifically Applied The Holding Of *Copperweld* To The Facts Of This Case.

Petitioners argue that the Fourth Circuit's decision "directly conflicts with and guts" this Court's holding in *Copperweld*. Pet. at 12. That argument is meritless and reflects a misreading of the Fourth Circuit's decision below. Contrary to the Petitioners' assertion, the Fourth Circuit clearly followed the principles set forth in *Copperweld*. App. 14a, 18a. It began by explaining that *Copperweld* held

that a corporation and its officers, a corporation and its unincorporated divisions, and a parent corporation and its wholly-owned subsidiary are legally incapable of conspiring because they have a "unity of purpose or a common design." App. 14a.

The Fourth Circuit then expressly applied the principles established in *Copperweld* to the specific facts in this case and held that "the medical doctors appointed to serve on Trigon's MCAP had a unity of interest with Trigon in "addressing clinical issues in a manner that would best serve [Trigon's] consumers, the plan enrollees."[9] App. 17a. The Fourth Circuit found that the MCAP was "without question a corporate agent of Trigon, chaired by a Trigon employee," and that "Trigon had 'ultimate control' over the MCAP's actions." *Id.* In fact, the Fourth Circuit said that this case presented even stronger reasons for applying the intracorporate immunity doctrine than in its *Oksanen*

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[9] The Petitioners claim that the Fourth Circuit's decision is inconsistent with *Copperweld* because "healthcare providers (like medical doctors, doctors of chiropractic, etc.) are necessarily separate and distinct economic actors vis-à-vis healthcare insurers." Pet. at 14. However, the fact that Trigon and the MCAP members are separate economic actors is not the relevant issue under *Copperweld*. Instead, the issue is whether Trigon and the MCAP members have a "unity of purpose" in the particular activity being challenged. The Fourth Circuit correctly applied this standard in evaluating the activities of the MCAP.

decision because the hospital and peer review committee were legally distinct entities in *Oksanen* whereas, in this case, the MCAP and Trigon were not. *Id.* The Fourth Circuit, again relying on *Copperweld*, concluded:

> American Chiropractic's argument paints with too broad a brush, and would, in effect, undercut much of the rationale of the intracorporate immunity doctrine by focusing on form over substance. Penalizing "coordinated conduct simply because a corporation delegated certain responsibilities to autonomous units might well discourage corporations from creating divisions with their presumed benefits."

App. 18a (quoting *Copperweld*, 467 U.S. at 771).

The Fourth Circuit's explicit reliance on *Copperweld* demonstrates that this case does not present an inconsistency with a Supreme Court decision or an unsettled question of federal law. Petitioners' challenge to the Fourth Circuit's decision is not based on a conflict with *Copperweld*, but rather is based on their disagreement with the Fourth Circuit's application of *Copperweld* to the facts of this case. The Petitioners' claim that the Fourth Circuit incorrectly applied *Copperweld* to the facts of this case, however, is not a proper or sufficient basis for the grant of certiorari because it asks the Court to determine whether the Fourth Circuit "misappl[ied] a properly stated rule of law." Sup. Ct. R. 10.

Furthermore, contrary to Petitioners' suggestion, this case does not present a proper vehicle for clarifying whether *Copperweld* applies to the more complex entities and corporate arrangements involving a high degree of corporate and economic integration that were at issue in *Fraser v. Major League Soccer, LLC*, 284 F.3d 47 (1st Cir. 2002). *Fraser* involved the complicated and unique relationship between a sports league and various operators/investors of individual teams in the league. This case is not similar to *Fraser* because it does not involve the types of complex arrangements and degree of economic integration between different corporate entities that were at issue in that case. Instead, this case involves only the extension of *Copperweld* to persons who, as the undisputed evidence demonstrated, were serving on a corporate committee and were acting as agents of Trigon. Accordingly, it would be improper for the Court to consider whether *Copperweld* reaches the types of complex arrangements described in *Fraser* because they are not relevant to this case.

B. This Court's Decision In *Allied Tube* Is Inapplicable To This Case.

Petitioners also challenge the Fourth Circuit's decision as contrary to *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492 (1988). However, that case

is completely inapposite to the issues presented in this case.[10] The *Allied Tube* decision related to the standard-setting activities of a private trade association. The trade association had set performance standards for electrical products, which were often incorporated into municipal fire codes. *Id.* at 495-96. A manufacturer of plastic electrical conduit sought to have the trade association list plastic conduit as an acceptable alternative to steel conduit in its code. *Id.* at 496. Manufacturers of steel conduit and other interested parties, however, agreed among themselves to recruit numerous individuals to join the trade association, pay those individuals' expenses and organize those individuals at the association's annual meeting as a bloc vote against the proposal to include plastic conduit in that year's code. *Id.* at 497. This Court held that the *Noerr-Pennington* doctrine did not protect the attempts by those manufacturers and other interested parties to influence the trade association's standard-setting activities and, thus, Section 1 of the Sherman Act applied to them. *Id.* at 501-02.

Petitioners argue that "[i]n *Allied Tube* . . . the Court held that when an association, like the MCAP, combines to set standards in an industry, like the Trigon-adopted back pain referral and treatment guidelines, the standards set by the combination has a 'serious potential for anticompetitive harm.'" Pet. at 13 (quoting *Allied Tube*, 486 U.S. at 505).

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[10] Not surprisingly, *Allied Tube* was not cited by any of the parties in the summary judgment or the appeal proceedings in the courts below.

This argument not only is incorrect, but also is based on a fundamental misstatement of the facts. First, the MCAP is not a trade or industry association. Rather, the MCAP is a formal corporate committee that was formed by Trigon. The committee is not legally distinct from Trigon and it had no decision-making authority. App. 17a-18a. Second, Trigon did not establish any industry standards. It only published an internal guideline that was offered to its contracting providers for use in connection with the treatment of Trigon's members. App. 10a. This clearly is not an industry standard-setting case because Trigon's guideline did not have any application or relation to any other healthcare insurance companies, their network providers, or their members. As a result, aside from the standard description of the meaning of a conspiracy under Section 1 of the Sherman Act, the *Allied Tube* decision does not have any relevance to the facts or issues in this case.

III. The Fourth Circuit's Decision Does Not Conflict With The Sixth, Eighth, Or Eleventh Circuit's Opinions.

The Petitioners contend that the case is certworthy because the Fourth Circuit's decision conflicts with decisions of the Sixth, Eighth, and Eleventh Circuits. This contention has no merit and misconstrues the issues relevant to this case.

The Sixth and Eleventh Circuits' decisions referenced by the Petitioners are hospital staff privileges

cases in which the intracorporate immunity doctrine was considered. The majority of the Circuits that have considered the application of the intracorporate immunity doctrine to hospital staff privileges cases have held that a hospital is legally incapable of conspiring with its medical staff. For example, the Fourth Circuit reached that conclusion in a separate decision in *Oksanen v. Page Memorial Hospital*, 945 F.2d 696, 703 (4th Cir. 1991) (en banc).

Similarly, the Sixth Circuit's decision in *Nurse Midwifery Associates v. Hibbett*, 918 F.2d 605 (6th Cir. 1990), also held that the intracorporate immunity doctrine bars an allegation of conspiracy between a hospital and its medical staff. Petitioners, however, misrepresent the holding in *Nurse Midwifery* by stating that "[t]he Sixth Circuit reversed [the District Court's] holding . . . that the hospitals were incapable of illegally conspiring because the doctors were 'agents' of the hospital and thus they were not separate actors able to combine or conspire." Pet. at 19. Contrary to the Petitioners' representation, the *Nurse Midwifery* opinion expressly states that "the intra-corporate conspiracy doctrine *prevents* a finding of conspiracy between a hospital and its medical staff." *Nurse Midwifery*, 918 F.2d at 614 (emphasis added). The Sixth Circuit held that the intracorporate immunity doctrine applied because "the members of the medical staff were acting as agents of the hospital."[11] *Id.* As

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[11] The Sixth Circuit also indicated that the intracorporate immunity doctrine "does not preclude a conspiracy among

a result, the Fourth Circuit's previous decision in *Oksanen*, involving hospital staff privileges, is entirely consistent with the Sixth Circuit. *Oksanen*, 945 F.2d at 703.

On the other hand, the Petitioners are correct that a few Circuits have held that a hospital is legally capable of conspiring with members of its medical staff in staff privileges cases, such as the Eleventh Circuit's decision in *Bolt v. Halifax Hospital Medical Center*, 891 F.2d 810, 819 (11th Cir. 1990), cited by Petitioners. However, the Petitioners' reliance on this conflict in the Circuits is misplaced and has no relevance to this case. The conflict in the Circuits relating to hospital staff privileges has no bearing on this case because it simply is not a hospital staff privileges case. There are a unique set of facts and considerations that are analyzed in determining whether the intracorporate immunity doctrine should apply to a hospital staff privileges case. Significantly, this case involves a different set of facts and circumstances. Therefore, this case is not a proper vehicle for this Court to resolve the conflict among the Circuits as to whether the intracorporate immunity doctrine should apply in hospital staff privileges cases.

The Petitioners also argue that the Fourth Circuit's

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individual members of the medical staff," *Nurse Midwifery*, 918 F.2d at 614, but that qualification is not applicable to this case because the Petitioners did not assert a conspiracy claim against any individual medical doctors.

decision conflicts with the Eighth Circuit's decision in *Mount Pleasant v. Associated Electrical Cooperative, Inc.*, 838 F.2d 268 (8th Cir. 1988). There is no conflict here because *Mount Pleasant* followed *Copperweld* and analyzed facts that are unrelated to the facts of this case. It did not involve the application of intracorporate immunity to an insurance company's appointment of medical doctors to a corporate committee; rather, it involved members of a cooperative electrical organization pursuing a common goal – the provision of low-cost electricity to its rural consumer-members. 838 F.2d at 276. The court found that there was no evidence that any generation-and-transmission cooperative defendant "ever pursued interests antithetical to those of the [rural electrical] cooperative as a whole." *Id.* The court also stated that the plaintiff had the burden to show that the defendant cooperatives had "pursued interests diverse from those of the cooperative itself." *Id.*

On the facts of that case, the Eighth Circuit applied the intracorporate immunity doctrine to bar the antitrust conspiracy claim because the plaintiff failed to show that any of the member cooperatives had acted inconsistent with the interests of the rural cooperative. *Id.* at 277. Applying the Eighth Circuit's analysis to this case, the same result would be reached because the Petitioners did not present any evidence that the medical doctors on the MCAP did anything that was inconsistent with Trigon's interests. Thus, there is no conflict between the two decisions as to the applicable law, and they also involve highly different factual settings.

Finally, the holding in this case is not in conflict with the decision of any other Circuit. In fact, it is entirely consistent with the only other Circuit that considered a similar set of facts, *Podiatrist Ass'n v. La Cruz Azul de P.R., Inc.*, 332 F.3d 6 (1st Cir. 2003). In *Podiatrist Ass'n*, the plaintiffs – a podiatric association and several podiatrists – complained that two health care insurance companies conspired with medical doctors who were involved in their corporate governance by excluding podiatrists and podiatric care from their basic health insurance coverages and by reimbursing podiatrists at lower rates than those paid to medical doctors for comparable services. 332 F.3d at 10-11. The evidence in *Podiatrist Ass'n* showed that one of the insurance companies had eight medical doctors on its nineteen-member Board of Directors and three medical doctors on its seven-member executive committee, which exercised responsibility over corporate policies between board meetings. *Id.* at 10. The other insurance company, before it changed its corporate governance structure, had seven medical doctors on its twenty-eight member board of directors; two medical doctors on its eight-member fees and contracts committee, which was responsible for proposing and evaluating benefits packages and reimbursement policies; and three medical doctors as the only members of its medical advisory committee. *Id.* The record also established that the insurance companies' respective boards of directors exercised ultimate control over all of their companies' major decisions concerning benefits and reimbursement rates. *Id.*

Based on these facts, the podiatrists argued that because independent medical doctors had occupied positions on the insurance companies' boards of directors, the fees and contracts committee and the medical advisory committee, the insurance companies had conspired with the medical doctors to institute the insurance policies that harmed podiatrists. *Id.* at 15-16.

The First Circuit analyzed the physicians' activities under *Copperweld*, and applied the intracorporate immunity doctrine to bar the conspiracy claims, holding that "agreements between two or more actors who operate within and for the benefit of a single economic enterprise do not satisfy the concerted action requirement of Section 1." *Id.* at 13. The First Circuit further explained that "the plaintiffs have not articulated a claim that involves anything more than activity occurring within a single enterprise." *Id.* at 14.

Like the podiatrists, the Petitioners here allege that medical doctors who served on a committee of an insurance company conspired with the company to harm chiropractors. In both cases, the Circuit Courts held that the intracorporate immunity doctrine barred the conspiracy claims because the medical doctors serving on the insurance company committees were acting within and for the benefit of a single enterprise. Accordingly, the only two Circuits that have examined this factual scenario have reached the same conclusion that the intracorporate immunity doctrine bars a conspiracy under these circumstances.

In sum, the Petition should be denied because the Fourth Circuit's decision is not in conflict with the decisions of the other Circuits, and is not a proper vehicle for addressing the different results reached in hospital staff privileges cases.

CONCLUSION

For the foregoing reasons, Trigon respectfully requests that this Court deny the Petition for Writ of Certiorari.

Respectfully submitted,

E. Duncan Getchell, Jr.*
Howard Feller
Bryan A. Fratkin
McGuireWoods LLP
One James Center
901 East Cary Street
Richmond, Virginia 23219
(804) 775-1000
Counsel for Respondents

**Counsel of Record*

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AMERICAN CHIROPRACTIC ASSOCIATION, INCORPORATED, a non-profit corporation, *et al.*,

Petitioners,

v.

TRIGON HEALTHCARE, INCORPORATED, *et al.*,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

REPLY TO BRIEF IN OPPOSITION

George P. McAndrews
Counsel of Record
Steven J. Hampton
Patrick J. Arnold, Jr.
Sharon Hwang
James P. Murphy
Peter J. McAndrews
Ronald A. Dicerbo
MCANDREWS, HELD & MALLOY, LTD.
500 West Madison Street
Suite 3400
Chicago, IL 60661
(312) 775-8000

Thomas R. Daly
ODIN, FELDMAN, & PITTLEMAN, P.C.
9032 Lee Highway
Suite 1100
Fairfax, VA 22031
(703) 218-2100

William G. Shields
THORSEN & SCHER
3810 Augusta Ave.
Richmond, VA 23230
(804) 359-3000

Counsel for Petitioners

THE LEX GROUP • 1108 East Main Street • Suite 1400 • Richmond, Virginia 23219
(804) 644-4419 • (800) 856-4419 • Fax: (804) 644-3660 • www.thelexgroup.com

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REPLY TO BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

The Petitioner, The American Chiropractic Association ("ACA"), provides this brief Reply to address an inaccurate assertion made by Respondent Trigon Healthcare, Inc.[1]

At pages 12 through 16 of its Brief In Opposition, Trigon Healthcare, Inc., *et al.* ("Trigon") inaccurately states that (1) ACA alleged only one antitrust conspiracy and (2) "the conspiracy" was rejected by the lower courts on independent grounds not raised in ACA's Questions Presented in its Petition For Writ Of Certiorari. Each part of Trigon's two-part assertion is false.

ACA Alleged Multiple, Separate Antitrust Conspiracies

ACA alleged multiple antitrust conspiracies. ACA alleged that Trigon conspired (1) with the individual medical doctors on the MCAP, and (2) with the Virginia medical associations and societies that were represented by the medical doctor representatives on the MCAP.

The first conspiracy alleged by ACA and addressed by the lower courts involved the medical doctors on the MCAP in their capacity as individual

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[1] Although Trigon makes several assertions believed to be inaccurate, Petitioner ACA addresses only one herein, because that one was not explicitly addressed in ACA's Petition For Writ Of Certiorari or by any amici, and requires prompt correction.

doctors. The Fourth Circuit explicitly recognized that ACA alleged a conspiracy between Trigon and the individual doctors on the MCAP:

> We consider first American Chiropractic's argument that Trigon conspired with medical doctors who served on the MCAP.

(App. 13a).

A second, separate conspiracy alleged by ACA was also addressed by the lower courts. ACA alleged that Trigon separately conspired with the various Virginia medical associations and societies ("medical associations"). The Fourth Circuit directly acknowledged this second, separate conspiracy when it stated:

> American Chiropractic next argues, assuming that the MCAP did not conspire with Trigon, that the medical associations who placed their members on the MCAP conspired with Trigon to publish the allegedly misleading guidelines and to implement several coverage policies aimed at limiting the usage and reimbursement of chiropractic services.

(App. 19a); (*see also* App. 62a-114a (Third Amended Complaint); and App. 13a-22a (Fourth Circuit Decision describing the multiple alleged conspiracies)). Thus, the initial premise underlying Trigon's entire argument

is faulty because the record shows that ACA alleged that Trigon engaged in multiple antitrust conspiracies.

Summary Judgment Was Granted As To Both Conspiracies Based On The Improper Extension of *Copperweld*

The second prong of Trigon's false assertion, that the lower courts rejected ACA's alleged conspiracies on independent grounds not raised in ACA's Questions Presented in its Petition For Writ Of Certiorari, is equally faulty. The lower courts rejected each separate conspiracy alleged by ACA by improperly concluding that the medical doctors on the MCAP were "agents" of Trigon under *Copperweld*.

The Fourth Circuit granted summary judgment on the first conspiracy, stating:

> [W]e look to whether the medical doctors, in their role as members of the MCAP, share a unity of interest with Trigon that makes them corporate agents of Trigon. We believe that they do.

(App. 17a).

The improper extension of *Copperweld* was also the basis for the lower courts' summary rejections of ACA's second asserted conspiracy between Trigon and the medical associations. The Fourth Circuit, in view of its first finding that the doctors were "corporate agents of Trigon," could not treat the doctors as representatives or agents of the medical associations. Thus, the court relied on an inapposite antitrust case,

and incorrectly viewed the doctors merely as members of the medical associations, stating:

> At most, the MCAP meeting shows contact between two independent economic actors, but mere contacts and communications, or the mere opportunity to conspire, among antitrust defendants is insufficient evidence of an anticompetitive conspiracy. *Cooper v. Forsyth County Hosp. Auth.*, 789 F.2d 278, 281 (4th Cir. 1986).

(App. 21a).[2] Yet, ACA asserted, and the record evidence shows, that the medical doctors on the MCAP were "appointed by" the medical associations, and represented the interests of the medical associations. (App. 1103a - 1104a).[3] The Fourth Circuit thus concluded (wrongly) that, because the medical doctors were "agents" of Trigon, summary judgment was also appropriate as to the second separate conspiracy alleged by ACA. (*See* App. 13a-22a).

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[2] The Fourth Circuit's reliance on *Cooper* is illustrative of its misunderstanding of antitrust law generally, and the alleged conspiracies specifically. *Cooper* is a case in which the evidence showed that medical doctors at a peer review committee meeting were simply members, not representatives, of a medical association. (*See Cooper v. Forsyth County Hosp. Auth.*, 789 F.2d 278 (4th Cir. 1986)).

[3] ACA's Petition (and Questions Presented) also challenge the underlying issue that the Fourth Circuit completely ignored the evidence presented (*see* Petition, at i and 16-18) showing that the medical doctors representing the Virginia medical societies on the MCAP were not employees or agents of Trigon. That is part and parcel of the fundamental *Copperweld* issue.

Conclusion

Trigon's argument, that the ACA alleged only one conspiracy, and that the Fourth Circuit rejected it on multiple independent grounds, is false. The Fourth Circuit recognized and summarily ruled on two separate conspiracies alleged by ACA. The Fourth Circuit rejected ACA's first alleged conspiracy based on the grounds that the medical doctors were agents of Trigon under *Copperweld*, and were therefore incapable of conspiring with Trigon. This conclusion then formed the basis for the Fourth Circuit's rejection of the second conspiracy alleged by ACA because, as agents of Trigon, the medical doctors could not be agents of the medical associations as well.

ACA's Petition For Certiorari should be granted because it presents extremely significant issues to the healthcare industry in this country, and is dispositive with respect to each conspiracy alleged in this case.

Respectfully submitted,

George P. McAndrews
Counsel of Record
Steven J. Hampton
Patrick J. Arnold, Jr.
Sharon Hwang
James P. Murphy
Peter J. McAndrews
Ronald A. Dicerbo
McANDREWS, HELD & MALLOY, LTD.
500 West Madison Street, Suite 3400
Chicago, Illinois 60661
(312) 775-8000

Thomas R. Daly
ODIN, FELDMAN, AND
PITTLEMAN, P.C.
9032 Lee Highway
Suite 1100
Fairfax, Virginia 22031

William G. Shields
THORSEN & SCHER
3810 Augusta Avenue
Richmond, Virginia 23230
(804) 359-3000

Counsel for Petitioners
AMERICAN CHIROPRACTIC
ASSOCIATION, AND VIRGINIA
CHIROPRACTIC ASSOCIATION,
ET AL.

(10)

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IN THE

Supreme Court of the United States

AMERICAN CHIROPRACTIC ASSOCATION, INCORPORATED, a non-profit corporation, *et al.*,

Petitioners,

v.

TRIGON HEALTHCARE, INCORPORATED, *et al.*,

Respondents.

On Petition For Writ of Certiorari
To The United States Court of Appeals
For the Fourth Circuit

AMICUS CURIAE BRIEF OF THE ASSOCIATION OF CHIROPRACTIC COLLEGES IN SUPPORT OF PETITIONERS

GEORGE J. MANNINA, JR.
Counsel of Record
O'CONNOR & HANNAN, L.L.P.
1666 K Street, N.W., Suite 500
Washington, D.C. 20006
Tel: (202) 887-1400, Fax: (202) 466-3215

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STATEMENT ON SUBMISSION

This Amicus Curiae Brief[1] is submitted on behalf of Petitioners with the consent of all of the parties.

INTEREST OF THE ASSOCIATION OF CHIROPRACTIC COLLEGES

If the decision of the United States Court of Appeals for the Fourth Circuit in American Chiropractic Ass'n, Inc. v. Trigon Healthcare, Inc., 367 F.3d 212 (4th Cir. 2004), is allowed to stand, member institutions of the Association of Chiropractic Colleges ("ACC") will be adversely affected in two ways. First, the number of men and women seeking admission to ACC institutions will diminish. Second, the default rate on the repayment of student loans will increase. These events will occur because the Trigon decision will result in diminished income to chiropractors, thereby making entrance into the profession less attractive and reducing the ability of recent graduates to earn the level of income necessary to repay federally insured student loans.

After completing prerequisite undergraduate collegiate courses, a student is eligible, if accepted, to enter a chiropractic college, which culminates in a first professional degree as a doctor of chiropractic. The ACC represents 16 U.S. institutions with a current enrollment of approximately 10,000 students. Graduates of ACC's accredited programs have completed four years of study in a clinical doctorate program.

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[1] Counsel of Record for the amicus curiae wrote this amicus curiae brief in its entirety. Counsel for other parties did not author any part of this brief. No person other that the amicus curiae made any monetary contribution to the preparation and submission of this brief.

While tuition costs vary among chiropractic institutions, an applicant for admission can expect to pay approximately $120,000-$130,000 to achieve his or her doctor of chiropractic degree. 90% of chiropractic students graduate with loans which average $100,000-$125,000. These loans are provided by lending institutions working with the academic institutions and are federally insured.

An increased default rate on these student loans will not only impact the federal budget but defaults above a certain level will also cause U.S. Department of Education officials to restrict or suspend an institution's eligibility to participate in the federal student loan guarantee program. Given the heavy dependence of chiropractic students on federally guaranteed loans to finance their education, this result would have a devastating effect on ACC's member institutions.

In addition, the primary lending institution to chiropractic students currently provides research scholarships to the institutions and loan recipients receive a very advantageous loan rate. Both of these positive aspects of the existing loan program would be jeopardized by an increased loan default rate.

Upon graduation, doctors of chiropractic expect to earn an adequate income allowing them to operate their businesses and, if necessary, to repay any outstanding loans from fees for service. Studies document that the inability to earn that expected income, and the additional burden of student loans, will decrease the number of undergraduate students seeking to become doctors of chiropractic, thereby reducing college enrollment and directly harming ACC member institutions.

ACC's member institutions are almost 100% dependent on tuition. Therefore, changes in enrollment have an immediate impact on the ability of the institutions to pay for the costs associated with providing an educational program, including faculty, research, and student services. Thus, economic forces which impact the decision of undergraduates to pursue a doctor of chiropractic degree are of enormous import to ACC, its members, and its students.

SUMMARY OF ARGUMENT

The Trigon decision improperly extends the intracorporate immunity doctrine by allowing two economically separate entities to conspire in a manner which would otherwise be in violation of the Sherman Act. Under Trigon, one entity can now create a committee comprised of representatives of the other entity and that committee can lawfully create or validate an otherwise proscribed anti-competitive policy.

ARGUMENT

A. Actions By Trigon Healthcare, Inc. Will Harm ACC And Its Member Institutions.

As noted above, the actions taken by Trigon Healthcare, Inc. ("Trigon"), upheld by the United States Court of Appeals for the Fourth Circuit, will harm ACC and its member institutions. The relevant facts which document Trigon's actions and intent are four.

First, recognize at the outset that Trigon is not in the business of evaluating the relative quality of healthcare provided. Instead, Trigon sells health insurance and has become Virginia's largest for-profit health insurance company. Appellants Opening Brief at 20, American

Chiropractic Ass'n. v. Trigon Healthcare, Inc., 367 F.3d 212 (4th Cir. 2004) (No. 03-1675), ("Appellants Brief"). Indeed, Trigon admits it does not make value judgments that one treatment is more efficacious than another. Appellees Brief at 5, American Chiropractic Ass'n v. Trigon Healthcare, Inc., 367 F.3d 212 (4th Cir. 2004) (No. 03-1675). Thus, it would be outside the proper scope of Trigon's legitimate business interest to pronounce judgments about what method of treatment is most appropriate for a certain medical condition.

Second, in 1994, the Agency for Health Care Policy and Research ("AHCPR"), an agency of the U.S. Department of Health and Human Services, did make a pronouncement about the most effective treatment for back pain. In a 170 page study titled "Acute Low Back Pain in Adults," AHCPR concluded that spinal manipulation was the most efficacious method of treating lower back pain. Appellants Brief at 21-22. Spinal manipulation therapy is a treatment provided by doctors of chiropractic. Trigon, 367 F.3d at 221-222.[2] The study was completed by a multi-disciplinary panel which included twelve medical physician experts. Appellants Brief at 21. During the two year study, abstracts of over 10,000 research papers were reviewed and almost 4,000 articles were specifically examined. Id. The professional journal of the American College of Physicians and the American Society of Internal Medicine stated that the AHCPR study "concluded that spinal manipulation therapy is the most effective and cost-effective treatment for acute lower back pain . . . ." Trigon, 367 F.3d at 221-222.

Third, even though Trigon admits it has no business interest in recommending one medical treatment over another, Trigon adopted a "referral" guideline governing to

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[2] Doctors of chiropractic have the most education and training in the assessment and treatment of spinal conditions.

whom medical doctors should refer lower back pain patients for treatment. Trigon claims its referral guideline was only a simplified restatement of the AHCPR report. However, in stark contrast to the AHCPR report which concluded that spinal manipulation was the most effective and cost effective treatment for back pain, Trigon's referral standard stated only that such treatment "may be as effective" as other forms of treatment. Trigon, 367 F.3d at 222.[3] Thus, despite admissions that Trigon was not in the business of evaluating the relative merits of competing treatment methodologies, Trigon did precisely that. Indeed, Trigon's guideline was considered to be "an informative practice guideline for physicians." Trigon, 367 F.3d at 221. Trigon then distributed its referral guideline to its participating medical doctors, (almost 90% of the medical doctors in Virginia). Appellants Brief at 10 and 38.

Fourth, there is enormous economic significance associated with the health care professional to whom a lower back patient is referred. Back pain is the second leading cause of visits to medical physicians. Id. at 24. Approximately 37% of all chiropractic patients seek treatment for back pain and a significant percentage of these patients seek an appointment with a doctor of chiropractic because they have been referred by a medical physician. Thus, when Trigon issued its pronouncement to its member doctors about how Trigon expected them to conduct their practice, there was little doubt it would have a significant impact on who earns fees for treating patients with back pain. In fact, unhindered referrals of patients by medical doctors would have resulted in the transfer of an estimated $60 million from medical physicians in Virginia to doctors of chiropractic. Appellants Brief at 25.

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[3] Trigon's referral guideline was not based on any independent analysis but was based exclusively on the AHCPR report. Appellants Brief at 38.

In summary, an entity supposedly without any interest in the selection of medical treatment did, in fact, prepare a treatment referral policy which deliberately misstated the consensus national study and which advantaged one group of providers, medical doctors, over another group, doctors of chiropractic. The effect of Trigon's policy was to inflict economic harm on doctors of chiropractic.[4]

Compounding the problem is the fact that Trigon's policy is to pay chiropractors 40% less than medical doctors are paid for the exact same diagnostic and treatment services, notwithstanding the consensus conclusions of the AHCPR study and notwithstanding the fact that doctors of chiropractic are a recognized branch of the healing arts. Trigon, 367 F.3d at 218; Appellants Brief at 23. Doctors of chiropractic are the only group of physicians to whom Trigon applies this reduction in payments. Thus, in competing for patients, doctors of chiropractic not only confront Trigon's referral policy, but they must also either reduce their income by reducing fees to the amount Trigon will pay, or expect patients who select chiropractic treatment to pay more out of their pocket. Either scenario has a negative impact on the fees doctors of chiropractic can expect to earn.

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[4] Trigon is the successor to Virginia Blue Cross and Blue Shield. Appellants Brief at 13. In 1962, the American Medical Association ("AMA") "aided by the National Association of Blue Shield Plans, began a 'lengthy, systematic, successful, and unlawful' national group boycott aimed at destroying chiropractic medicine." Trigon, 367 F.3d at 219, quoting Wilk v. Am. Medical Ass'n., 895 F.2d 352, 371 (7th Cir. 1990). In another context the United States Court of Appeals for the Fourth Circuit condemned Virginia Blue Cross and Blue Shield for anti-competitive conduct in attempting to adopt policies favoring one group of caregivers over another. Virginia Academy of Clinical Psychologists v. Blue Shield of Virginia, 624 F.2d 476 (4th Cir. 1980).

Simply put, Trigon decided to pay less for the treatment the AHCPR study found to be the most effective. In other words, Trigon decided to increase its operating costs by paying more for less effective treatment. This is illogical business behavior. Trigon's action, particularly when coupled with Trigon's deliberate misrepresentation of the AHCPR study, is indicative of an intent to disadvantage doctors of chiropractic vis-à-vis medical doctors.

B. Trigon Conspired With Medical Doctors To Inflict Harm Upon Chiropractors, Including ACC And Its Member Institutions.

Trigon's actions described above were not taken unilaterally. Trigon effectively collaborated and conspired with medical doctors to harm doctors of chiropractic and, therefore, ACC and its member institutions. The facts, in addition to those stated above, are these.

First, although doctors of chiropractic are recognized by statute as a branch of the healing arts, there is a long and deep "history of animus from medical doctors and insurers aimed at chiropractors." Trigon, 367 F.3d at 218. The courts have found that medical doctors and insurers have engaged in a systematic and unlawful boycott aimed at destroying chiropractic medicine. Id. at 219. One court involved in the litigation surrounding those findings went so far as to issue an injunction to protect doctors of chiropractic. Wilk v. Am. Medical Ass'n., 671 F. Supp. 1465 (N.D. Ill. 1987), aff'd., 895 F.2d 352 (7th Cir. 1990), cert. denied, 496 U.S. 927 (1990). Given this legal history and injunction, it is not surprising that medical doctors and insurers take great effort to disguise their antipathy toward doctors of

chiropractic who are a direct competitor with medical doctors in providing services to patients suffering back pain.

Second, Trigon convened its Managed Care Advisory Panel ("MCAP") to review its back pain referral guidelines so that Trigon could claim its policy was endorsed by an independent panel of experts, which is precisely what Trigon did. However, the composition of the MCAP committee virtually guaranteed the result. MCAP had fifteen members, nine of whom were "independent medical doctors appointed by professional organizations" of medical doctors. Trigon, 367 F.3d at 221. Trigon itself characterized these nine medical doctors serving on MCAP as "representatives" of medical associations who had been "appointed by" these associations. Appellants Brief at 26. The medical doctors on MCAP represented associations whose members were in direct competition with doctors of chiropractic. No chiropractors served on MCAP.[5]

Third, although MCAP had no decision making authority within Trigon, it was a committee to which Trigon turned for independent review of Trigon policies. Thus, when Virginia's medical doctors received Trigon's back pain treatment and referral guidelines stating that chiropractic treatment "may be" as effective as other forms of treatment, they received the guidelines with Trigon's proud claim that the guidelines had been "approved and endorsed" by MCAP. Trigon, 367 F.3d at 222. Trigon treated MCAP as an independent review panel and effectively represented it as such.

In sum, Trigon materially altered the AHCPR findings and then gave the altered findings to a review board

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[5] Of Trigon's six employees serving on MCAP, four were medical doctors.

comprised of economic competitors of chiropractic medicine for review. Trigon then told its participating medical doctors, 90% of Virginia's medical doctors, that its referral guidelines had been independently reviewed and approved. While Trigon may have stated its referral guidelines were based on the AHCPR report, no one on the select MCAP, least of all the medical doctors serving as representatives of their medical associations, could have been unaware of the true findings of the AHCPR report. Thus, Trigon, working with MCAP, issued a false report which caused economic harm to doctors of chiropractic and to ACC and its member colleges.

C. The Legal Principle Adopted By the Appeals Court Is Incorrect.

If Trigon had acted in concert with an association of medical doctors to place chiropractors at a competitive disadvantage, the result would be the same as in Wilk v. Am. Medical Ass'n., 895 F.2d 352 (7th Cir. 1990), where the court found that a national association of medical doctors had conspired with health insurance companies to inflict economic harm on doctors of chiropractic. The question before this Court is whether the result should be any different simply because the health insurer, rather than working directly with an association of medical doctors, created a committee to which the association of medical doctors appointed its "representatives." The United States Court of Appeals for the Fourth Circuit held that such a procedural deception was sufficient to circumvent this nation's antitrust laws.

The Appeals Court found that the committee Trigon created was a Trigon committee and, under the intracorporate immunity doctrine, Trigon could not commit an antitrust violation because Trigon could not conspire with

itself. Contrary to the holding in Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752 (1984), this argument opens a gaping hole in our nation's antitrust laws.

When this Court announced the intracorporate immunity doctrine with respect to corporations and their wholly owned subsidiaries in Copperweld, this Court stated it was deciding the "narrow issue" of "whether a parent and its wholly owned subsidiary are capable of conspiring in violation of § 1 of the Sherman Act." Id. at 767. The Court's decision turned on the fact that all of the players in the alleged conspiracy were officers and employees of the same corporate entity. Id. at 769-771. The Court noted that it was irrelevant if a parent corporation operated through subsidiary companies because the parent could, at any time, assert control over the subsidiary. Id. at 771-772. In considering these issues, the Court cautioned against elevating form over substantive reality. Id. at 772.

The facts underpinning Copperweld are absent here. Here, there is no parent and no controlled subsidiary consisting of employees of the parent. Instead, there is a committee where majority control is vested in people who are considered by Trigon to be "representatives" of separate and independent entities. None of these representatives are officers or employees of Trigon. Indeed, when Trigon altered the national consensus AHCPR study to create its own referral guidelines, Trigon bragged that its referral guideline had been approved by this committee, effectively treating this committee as an independent entity. For the Fourth Circuit to find that Trigon's actions fall within the protection of Copperweld elevates form over substance.

If the ruling of the United States Court of Appeals for the Fourth Circuit prevails, it opens the door to independent economic entities avoiding the Sherman Act's prohibitions

by simply having one entity create a committee controlled by representatives of the other entity, and then having the first entity adopt the findings of the committee. Such a result vitiates Section 1 of the Sherman Act by extending Copperweld into the nether region of strained interpretations.

Allowing the Fourth Circuit's decision to stand also undermines this Court's ruling in Allied Tube and Conduit Corp. v. Indian Head, Inc., 486 U.S. 492 (1988). There, members of a private standard setting association met to adopt a standard for the economic benefit of certain members. Again, this Court chose to examine closely the "context and nature" of the activity and found the standard setting committee had improperly exercised market power because one group had "stacked" the Committee. Id. at 504-508. Importantly, the Court found that an association cannot validate its anti-competitive activities by claiming it has unbiased procedures when, in reality, its procedures allow economically interested parties to use the process to disadvantage competitors. Id. at 509.

In the instant case, Trigon created a committee, allowed competitors of doctors of chiropractic to stack the committee with its representatives, asked the committee to approve a biased and incorrect referral guideline, and then adopted the guideline as its own, proclaiming to all that the guideline had been approved by a review committee. The parallels to Allied Tube and Conduit are striking. Yet, the Appeals Court decision in Trigon reached a different result, effectively nullifying this Court's ruling in Allied Tube and Conduit, and providing a clear pathway for persons to circumvent that decision.

CONCLUSION

This Court should grant the Petition for Certiorari to prevent its decisions in Copperweld and Allied Tube and Conduit from being overturned and to prevent Trigon and its allied medical doctors from collaborating to inflict economic harm on ACC and its students.

Respectfully submitted,

George J. Mannina, Jr.
Counsel of Record
O'CONNOR & HANNAN, L.L.P.
1666 K Street, N.W., Suite 500
Washington, D.C. 20515
Tel: (202) 887-1400, Fax: (202) 466-3215

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Respondents.

ON PETITION FOR WRIT OF CERTIORARI
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FOR THE FOURTH CIRCUIT

BRIEF AMICI CURIAE OF FORTY-SIX CHIROPRACTIC PROFESSIONAL ASSOCIATIONS AND THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION IN SUPPORT OF PETITIONERS

Jonathan B. Sprague
Counsel of Record
Mark L. Mattioli
James Kutz
POST & SCHELL, P.C.
Four Penn Center
1600 John F. Kennedy Boulevard
Philadelphia, Pennsylvania 19103
(215) 587-1155

Counsel for Amici Curiae
Listed in Appendix

THE LEX GROUP^{DC} ♦ One Massachusetts Ave., NW ♦ Suite 670 ♦ Washington, DC 20001
(202) 789-2400 ♦ Fax: (202) 789-1911 ♦ www.thelexgroupdc.com

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INTRODUCTION AND INTEREST OF AMICI CURIAE

The amici chiropractic professional associations represent doctors of chiropractic from all across the nation.[1] Also joining amici is the National Community Pharmacists Associates.[2] These organizations seek to promote, and insure the survival of, chiropractic as a healing profession. The question presented by this case – whether *Copperweld*[3] immunizes the conspiracy between Trigon and medical specialty societies to ensure that patients with musculoskeletal conditions are diverted to medical doctors instead of doctors of chiropractic and to otherwise economically discriminate against doctors of chiropractic by, among other things, implementing annual medical expenditure caps and underpayments – is of the greatest concern to all state chiropractic professional association members, their patient participants in health plans, and, indeed, to all health care consumers in the United States.

SUMMARY OF ARGUMENT

This case involves a conspiracy between Trigon and the Virginia state medical societies and schools to retard, deter and inhibit referrals by medical doctors to chiropractors and represents a concerted effort by medical physicians and Trigon, through punitive and discriminatory insurance reimbursement and referral policies, to drive chiropractors out of the market. *Copperweld* does not

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[1] In letters of consent filed with the Clerk, the parties have consented to the filing of this amici brief. Under this Court's Rule 37.6, amici state that this brief was not authored in whole or in part by counsel for a party and that no one other than amici made a monetary contribution to the preparation or submission of this brief.

[2] The identities of the numerous amici are set forth in the Appendix bound with this brief.

[3] *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 104 S. Ct. 2731 (1984).

immunize Trigon's and the Medical Establishment's conspiratorial anticompetitive conduct. Otherwise, insurance companies, which co-conspire with the Medical Establishment, will continue to discriminate against chiropractic based upon reimbursement and referrals – with this *Copperweld*-protected conspiracy's ultimate goal being the marginalization, and eventual elimination, of the chiropractic profession.

ARGUMENT

I. Medical Physicians And Their Co-Conspirator Insurance Companies Should Not Be Permitted To Use *Copperweld* To Shield Themselves From Antitrust Scrutiny Especially Given The Medical Profession's 40-Year Campaign To Liquidate The Chiropractic Profession.

This Petition must not, indeed cannot, be viewed in a vacuum. This dispute is emblematic of a nationwide conflict between physicians (that is, the Medical Establishment) and competing allied health care participants in sundry health care markets including, but not limited to, chiropractors. For many years, osteopaths, certified registered nurse anesthetists, midwives, and podiatrists, among others, have accused the Medical Establishment of acting anticompetitively by denying them hospital staff privileges and/or excluding their care from reimbursement under insurance coverage. *Weiss v. York Hospital*, 745 F.2d 786 (3d Cir. 1984) (exclusion of osteopaths), *cert. denied*, 470 U.S. 1060, 105 S. Ct. 1777 (1985); *Oltz v. St. Peter's Community Hospital*, 861 F.2d 1440 (9th Cir. 1988) (exclusion of nurse anesthetists); *Nurse Midwifery Ass'n v. Hibbett*, 918 F.2d 605 (6th Cir. 1990) (exclusion of midwives), *cert. denied*, 502 U.S. 952, 112 S. Ct. 406 (1991); *Cooper v. Forsyth County Hospital Auth., Inc.*, 789 F.2d 278 (4th Cir. 1986) (exclusion of podiatrists), *cert. denied*, 479 U.S. 972, 107 S. Ct. 474 (1986).

The Medical Establishment's anticompetitive animus and exclusionary practices against osteopaths, nurse anesthetists, midwives and podiatrists, however, pale in comparison to its long-running eliminationist trade war against low cost, highly competitive chiropractic providers. The chiropractic profession's current lawsuit against Trigon Blue Cross/Blue Shield (now Anthem) is yet another battle in the chiropractic profession's long struggle for survival against the Medical Establishment's stifling, anticompetitive trade restraints. This beleaguered profession's very survival stands in the balance.

If the Medical Establishment wins this battle, the losers will be not only the chiropractic profession but, even more importantly, the million of consumers of chiropractic care -- care, which has been shown, in study after study, as being more cost-efficient and effective than comparable physician services. Consumers will be the biggest losers.

At issue are palpably anticompetitive insurance reimbursement and referral policies, ones fashioned by anticompetitive physicians, their medical associations and their insurance/reimburser organizations (*e.g.*, Trigon), which are designed and intended to limit reimbursement and referrals to chiropractors for the benefit of medical physicians and to the great harm of health care consumers nationwide.

The Medical Establishment's challenged restraints in Trigon must be viewed in the context of the long, sordid history of restraints imposed by the Medical Establishment and their proxies, whether hospitals or insurance companies, on chiropractors. The Medical Establishment's historical efforts to completely eliminate chiropractic as alternative, competing medical services cannot be ignored. Because physicians, historically, have excluded chiropractors without justification, the Fourth Circuit, in *Ratino v. Medical Service*, 718 F.2d 1260, 1272 (4th Cir. 1983),

directed the district court to consider, among other things, "[t]he history of the restraint." The Fourth Circuit, ironically, gave short shrift to this extensive restraint history in Trigon.

In 1990, the United States Court of Appeals for the Seventh Circuit, in affirming a nationwide injunction against the American Medical Association ("AMA"), characterized the Medical Establishment's national campaign to boycott chiropractic as "lengthy, systematic, successful, and unlawful." *Wilk v. AMA*, 895 F.2d 352, 371 (7th Cir. 1990), *cert. denied*, 496 U.S. 927, 110 S. Ct. 642 (1990).

According to the Wilk district court, the Medical Establishment's purpose for the boycott, which originated in the mid-1960's, was

> to contain and eliminate the chiropractic profession. This conduct constituted a conspiracy among the AMA and its members and an unreasonable restraint of trade in violation of Section 1 of the Sherman Act.

Wilk v. American Medical Association, 671 F. Supp. 1465, 1470 (N.D. Ill. 1987), *aff'd*, 895 F.2d 352 (7th Cir. 1990), *cert. denied*, 496 U.S. 927, 110 S. Ct. 2621 (1990). In short, the Medical Establishment was found guilty of attempting to first marginalize and then eliminate an entire profession. Today, the goals – marginalization and eventual elimination – remain the same. Only the methods have changed.

The chiropractic profession's challenge in the 1970's and 1980's was to turn back the "ethics-based," anti-referral boycott against the profession as reflected in Wilk:

> In 1967, the AMA Judicial Council issued an opinion under Principle No. 3 specifically holding that it was unethical for a physician to associate professionally with chiropractors

> . . . . Associating professionally would include making referrals of patients to chiropractors . . . . This opinion . . . was widely circulated to members of the AMA . . . . The opinion on chiropractic was also sent by the AMA to 56 medical specialty boards and associations.

Id. at 1473-74 (internal punctuation and record citations omitted).

The end result of this professional ethics anti-referral boycott of chiropractic was the following:

> Through such mechanisms, individual physicians were discouraged from cooperating with chiropractors in patient treatment, because referrals were inhibited by defendants' activities; . . . referrals from medical doctors were reduced. The product demand for chiropractor services was negatively effected.

Id. at 1479. Trigon, by its anticompetitive reimbursement and referral practices, also seeks, in conspiracy with the Medical Establishment, to reduce to zero "product demand for chiropractic services."

The Medical Establishment's now discredited ethics-based boycott was a failed attempt to steer as many patients as possible away from chiropractors. The Medical Establishment has the same anticompetitive goal, today. The only difference is that insurance reimbursers like Trigon have replaced AMA "ethical" rules as the Medical Establishment's preferred vehicle for liquidating this profession.

As the anti-referral "ethics" prescriptions found to violate the antitrust laws in Wilk were intended to

marginalize and eliminate the chiropractic profession, the "reimbursement and referral" policies adopted by Blue Cross/Blue Shield plans (including, but not limited to, Trigon) are designed to limit and contain the growth of chiropractic reimbursement in the face of growing public recognition and acceptance of comparably more effective, low cost chiropractic treatment for common conditions such as back pain. If chiropractic's challenge in the 1970's and 1980's was to thwart the Medical Establishment's ethics boycott against the profession, the challenge, today, is to rebuff the Medical Establishment's insurance-based "coverage" and ""reimbursement" boycott while hiding behind *Copperweld*. *Copperweld* immunity, however, should not be used as a license to destroy a profession.

Blue Cross/Blue Shield has long been considered the Medical Establishment's insurance company, to the exclusion of chiropractors and other non-medical physicians. *See, e.g., Virginia Academy of Clinical Psychologists v. Blue Shield of Virginia*, 624 F.2d 476, 485 (4th Cir. 1980) (Trigon's predecessor refused to reimburse for clinical psychologists' services unless billed through a physician), *cert. denied*, 450 U.S. 916, 101 S. Ct. 1360 (1981); App. 75a-84a. The growing evidence of low cost chiropractic clinical superiority and the establishment of higher relative values for chiropractic manipulation, however, economically threatened continued medical physician reimbursement dominance under these physician-friendly plans.

Anti-competitive, anti-chiropractic referral and reimbursement policies were soon adopted, by many health care plans, that treated chiropractic physicians as second-class providers in terms of referrals and reimbursement. It was again "open season" on chiropractors and, by extension, their patients.

The discriminatory reimbursement and referral policies adopted by Trigon Blue Cross/Blue Shield of

Virginia and the Medical Establishment, were particularly harsh, repressive and anti-competitive:

- Paying chiropractors forty (40%) percent less than medical doctors for the same services;
- Failing to pay for all services rendered;
- Applying an arbitrary $500 cap on manipulation services provided by chiropractors; and
- Failing to pay for the services rendered by a chiropractic assistant while paying for the equivalent services rendered by a medical assistant.

App. 1105a-1153a.

This stark economic discrimination shares similarities with anti-chiropractic policies adopted by Blue Cross/Blue Shield plans in other states. These discriminatory policies, written and drafted with the cooperation of medical competitors, sought to limit chiropractic reimbursement in a way no other provider's reimbursement is limited. Whether the issue is percentage limitation or caps on reimbursement or in failing to pay for the services rendered by a chiropractic assistant, these disparate reimbursement schemes have all been crafted by physician-friendly Blue Cross/Blue Shield plans and other insurance companies as a means by which chiropractors and chiropractic services may be limited, contained and, in time, eliminated -- all for the Medical Establishment's anticompetitive benefit.

As the anti-referral "ethics" prescriptions found to violate the antitrust laws in Wilk were intended to marginalize and eliminate the chiropractic profession, the discriminatory "economic" referral and reimbursement policies adopted by Blue Cross/Blue Shield plans in the

1990's were intended to marginalize and eliminate the chiropractic profession in light of growing pubic recognition and acceptance of chiropractic treatment. The restraint has simply mutated over time.

Consumer welfare is the Sherman Act's touchstone. This Court, in *Apex Hosiery Co. v. Leader*, 310 U.S. 469, 60 S. Ct. 982 (1940), well-stated the consumer welfare goal of the antitrust laws:

> The end sought [by the Sherman Act's prohibition against unreasonable restraint of trade] was the prevention of restraint to free competition in business and commercial transaction which tended to restrict production, raise prices or otherwise control the market to the detriment of purchasers or consumers of goods and services, all of which had come to be regarded as a special form of public injury.

Id. at 493 (emphasis added).

The central purpose of the antitrust laws is to preserve competition and, by extension, advance consumer welfare. It is competition that is vital to the public interest and every precedent in the antitrust field recognizes that the untrammeled interaction of competitive forces is what will, in the end, benefit consumers. The Fourth Circuit, in its cursory treatment of *Copperweld*, ignored not only the history of the restraint, as exemplified by the Medical Establishment's 40-year effort to eliminate chiropractic competition but also ignored the extremely harmful impact its *Copperweld*-based decision would have on consumer welfare. At least for those states in the Fourth Circuit, the Trigon Decision immunizes insurance companies as they, in doing the Medical Establishment's bidding, economically

discriminate against chiropractic in reimbursement and referral practices.

Consumer welfare, in the antitrust context, recognizes that consumers should be able to choose their preferred products or services, rather than have their choices made by well-entrenched, dominant providers. *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 459, 106 S. Ct. 2009 (1986). This Court, for example, in *National Society of Professional Engineers v. United States*, 435 U.S. 679, 98 S. Ct. 1355 (1978), rejected a defendant professional association's attempt to justify its ban on competitive bidding by asserting that consumers would be unable to distinguish between good and bad architects if architects were allowed to compete on price. *Id.* at 693-95.

It is consumers, not competitors, who possess the right to decide who competes with whom. If this Court denies this Petition, however, cost effective, high quality chiropractic services will be effectively denied to millions of people who reside in the Fourth Circuit. The loser would be not only the chiropractic profession but, more importantly, consumers of clinically proven chiropractic services. The Medical Establishment's long-held goal to marginalize and eliminate chiropractic as an will have been, in large part, realized.

Trigon, through its physician-dominated reimbursement and referral policies, is functionally excluding, through starkly discriminatory reimbursement and referral policies, a targeted class of competitors. The end result of this structural conspiracy is that many consumers are deprived of the much needed services of chiropractic doctors. Subscribers of Trigon and of other plans (who substantially limit chiropractic reimbursement and referrals), and who would prefer the services of a chiropractor find themselves effectively denied these essential services. These frustrated consumers' only

alternative is to go outside the plan and pay an out-of-pocket premium for chiropractic services, which results in higher overall prices.

Trigon's fundamental disregard of consumer welfare was underscored in the testimony of Trigon's Chief Medical Officer, William Bracciodieta, M.D. Dr. Bracciodieta, when asked whether Trigon evaluated the effects on its insureds "of its insurance coverages or lack of coverages on the healthcare provided," responded: "No. Again, that's not the business that we're in." (Petitioners' Fourth Circuit Brief at 37).

Trigon's denial of consumer chiropractic choice is particularly egregious in light of the health care industry's well-established recognition of chiropractic care's effectiveness. In 1994, for example, the Agency for Health Care Policy and Research ("AHCPR") of the U.S. Department of Health and Human Resources issued a 170-page study entitled "Acute Low Back Pain in Adults," along with an accompanying 30-page "Quick Reference Guide for Clinicians", entitled "Acute Low Back Problems in Adults: Assessment and Treatment." App. 798a-1040a, 1041a-1071a.

The AHCPR Study was conducted by a multidisciplinary panel comprised of twelve (12) medical physician experts, and other healthcare professionals and consumer representatives, who were brought together by the Agency for Health Care Policy and Research to perform an evidence-based analysis of all research trials and treatment approaches to acute low back pain in adults. Abstracts of over 10,000 research papers were reviewed, and almost 4,000 articles were retrieved. App. 798a-809a, 819a-822a.

The AHCPR study took nearly two years to complete. The findings and recommendations were given and included in Table 2 of the Quick Reference Guide of

Clinicians. Recommendations were for acetaminophen and, among other things, "manipulation." App. 802a-804a, 1041a-1071a.

Significantly, the AHCPR Study specifically identified and defined the recommended spinal manipulation as the type of manipulation used by all chiropractors:

> Spinal manipulation includes many different techniques. For this guideline, manipulation is defined as manual therapy in which loads are applied to the spine using short and long lever methods. The selective joint is moved to its end range of voluntary motion, followed by application of an impulse loading. The therapeutic objectives of manipulation include symptomatic relief and functional improvement.

App. 859a. This "functional improvement" is what gets patients back to work faster and at less expense. The Rand Corporation, in a separate study, concluded that chiropractors offered 90% of the recommended manipulation services in the United States. App. 156a, 158a, 211a.

Despite the AHCPR Study's endorsement of chiropractic, Trigon and the Medical Establishment in a concerted effort to prevent referrals from medical doctors to chiropractors, published the Trigon Guidelines, which obfuscated and obliterated the AHCPR-endorsed chiropractor-provided manipulative therapy. App. 1122a-1125a.

Trigon's contention that it had no economic motivation to harm chiropractors or to steer patients to medical doctors and away from chiropractors is rubbish.

Trigon's largest cost category is payment to healthcare providers. Trigon elected to pay chiropractors forty (40%) percent less than medical doctors for the identical service despite the chiropractors' superior skills in these areas as recognized, among other things, by the 1994 AHCRP Study. App. 1128a.

If Trigon was motivated only by economic concerns, it would not pay medical doctors more to provide inferior care than it pays chiropractors to provide superior care. That Trigon pays medical doctors more demonstrates that Trigon is not making an independent economic judgment. It is, rather, making a collusive judgment in combination with medical doctors – one that poses harm to patients and losses to chiropractors, all for the gain of medical doctors.

In light of the Medical Establishment's long, eliminationist trade war against chiropractors, this Court should not allow the Medical Establishment, through its insurance vehicle, Trigon, to finish what the AMA started 30-years ago: the marginalization and eventual elimination of the chiropractic profession.

If this Petition is denied and the Medical Establishment is permitted to conspire with insurance companies shielded behind *Cooperweld*, the Medical Establishment will, through this "reimbursement and referral" conspiracy, economically discriminate against, marginalize and ultimately eliminate chiropractors. The Medical Establishment would then be free to provide inferior care at higher cost without fear from rivals. Consumers, the ultimate losers, will be effectively denied reimbursed low cost, high quality chiropractic care.

The Medical Establishment's long sought goal – the liquidation of the chiropractic profession – will be one step closer to realization.

II. Trigon's $500 Cap, Along With Its Refusal To Pay For Increased Services, Has The Potential To Reduce Inputs Without Any Corresponding Consumer Benefit

Trigon's policies regarding chiropractors have the potential to create devastating anti-consumer effects in the Virginia market. In this regard, Trigon has instituted a policy that caps payment for chiropractic services at $500.00 per year. A cap on the amount of services will, in reality, only deter the provision of beneficial services to consumers. While it is not atypical for Managed Care Organizations such as Trigon to make efforts to reduce costs, such reductions, combined with the fact that Trigon is certainly one of the largest payors in Virginia, have a monopsonistic effect on the input market for acute back-pain services. *Mandeville Island Farms, Inc. v. American Crystal Sugar Co.*, 334 U.S. 219, 68 S. Ct. 996 (1948) (price fixing in input market for sugar beets).

In addition, Trigon's cap does not exist in a vacuum. Rather, in this case, the policies must be considered along with Trigon's refusal to pay for chiropractic services based upon the complexity of the services performed, thereby engaging in price discrimination with regard to chiropractic services. Trigon will compensate physicians based upon the complexity of the services, but refuses to do the same for chiropractors. While Trigon attempts to legitimize this policy based upon the amount of training and expense incurred by allopaths and other practitioners, the fact is that in a competitive market, price is determined by the amounts consumers are willing to pay. A capitalistic economy does not, and cannot, purport to weigh or judge the perceived merits of goods or services purchased by consumers. That the services may be outside of what Trigon views as the traditional paradigm should not drive the competitiveness of the pricing. If medicine were reduced to the traditional paradigm, innovation would not occur.

In essence, this is exactly what Trigon is doing in this case. Despite the fact that numerous independent studies have demonstrated that a percentage of consumers prefer to receive services from chiropractors, it has instead sought to discriminate against these services because chiropractors are perceived as receiving a less expensive education. Trigon has, in essence, substituted its judgment for the judgment of consumers. Thus, Trigon's preemptive judgment has limited consumer choice.

The concern is that these policies can easily be applied to other forms of treatment involving other practitioners and any new form of treatment.

In fact, much of the philosophy of managed care is to avoid new or different treatment options. This type of behavior, when engaged in by an MCO in a purely competitive market, can be easily disciplined by consumer choice. Here, however, because Trigon is alleged to be a dominant player in this market, consumers have less of an opportunity to switch health insurers. App. 79a. The consumer realities of these types of choices were not appropriately considered by the District Court or the Fourth Circuit Court of Appeals in this matter. Unfortunately, a jury was not permitted, as it should have been, to address these issues which are critical to all health care providers.

Dr. Leonard G. Schifrin, Chancellor Professor of Economics, Emeritus, of the College of William & Mary, in his report, discussed the potential output-reducing ramifications of the caps:

> Reimbursement caps or limitations, if set at restrictive levels, can impose heavy financial penalties on patients and also on chiropractors. Trigon has imposed a cap on payments for spinal manipulation of $500 per year per insured individual. In other words,

> Trigon will pay a total of no more than $500 to any and all chiropractors for therapy for a Trigon-covered individual in a given year regardless of how much treatment is necessary to remedy the problems suffered by that person. . . . Obviously, this will curtail the demand for chiropractic services, redirecting patients to other types of providers such as medical doctors at the outset or during their chiropractic treatment, or perhaps causing patients to halt their therapy entirely when the $500 limit is reached.

App. 1119a.

Antitrust jurisprudence has largely ignored the effects a dominant buyer can have on the input market. In large respect, this is due to notions in the case law that an insurer, such as Trigon, is merely an agent acting on behalf of the insured. *See Kartell v. Blue Shield of Massachusetts, Inc.*, 749 F.2d 922, 925 (1st Cir. 1984). In fact, this view appears to dominate antitrust thinking with regard to dominant buyers in the health care setting. That is, they are acting on behalf of their members. This notion is outdated.

While the concept that a health insurer acts as an agent for its insured may have been valid twenty years ago when now-Justice Breyer authored *Kartell*, current payor/relations have changed such that insurers, especially managed care organizations, cannot be viewed as agents of insureds. Indeed, in the ensuing twenty years, the industry has witnessed a remarkable increase in the number of "patient rights" laws designed to provide managed care members with access to care.[4] Thus, in today's

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[4] *See, e.g.*, 40 Pa. Stat. §§ 991.2101 *et seq.* (typical of Acts passed to protect patients).

environment, insurers, such as Trigon, have every incentive to reduce the care provided to members. Accordingly, the paradigm once thought applicable to health care financing organizations is no longer valid.

Professors Hammer and Sage identified this issue and the problems it creates in today's environment, in a recent article:

> Because the case involves insurance benefits rather than more typical goods or services, [Justice] Breyer never sees Blue Shield as buying inputs from suppliers in order to create and sell a final product to consumers. Two decades of hindsight with respect to the evolution of the health insurance industry reveal this to be a staggering omission. Managed care is all about integrating the financing and delivery of health care services into a single product. Moreover, market structure and competition have direct implications for the fidelity of [the court's] principal-agent relationship between insurer and insured. The exercise of monopsony power can be a form of agency failure, particularly if it contributes to higher prices or reduced output in the final product market. The monopsonist maximizes its own surplus, not the surplus or utility of its customers.

P.J. Hammer & W. Sage, *Monopsony as an Agency and Regulatory Problem in Health Care*, 71 Antitrust L.J. 949, 962 (2004). *See also* R.D. Blair and J.B. Herndon, *Physician Cooperative Bargaining Ventures: An Economic Analysis*, 71 Antitrust L.J. 989, 998 (2004) (to maximize profit, a monopsonist will effectively buy a smaller quantity of

inputs and pay less for those inputs, thereby benefitting MCO's to the detriment of consumer welfare).

Where savings are passed on to consumers as a result of lower prices, naturally, the monopsony problem does create significant consumer welfare issues. In cases of a profit maximizing insurer such as Trigon, however, there is no incentive to pass these savings on to consumers. Arguably, the cap in this case has the exact opposite effect and may actually drive prices to consumers up instead of down.

For example, the cap prevents patients from obtaining services from chiropractors in excess of $500. Unless the patient is willing and financially able to pay for such services on his or her own, the patient must face a difficult choice: forgo treatment altogether or obtain less efficient treatment from a higher cost provider. Because the caps do not apply to other health care practitioners, the result can only be that the patient will obtain higher cost services from other providers. While a profit maximizing insurer would have no motive to pass on cost savings to consumers, it would have every incentive to pass on the additional costs to consumers, whether directly to the members through higher co-payments or through higher premiums to employers.

The end result is that dominant insurers profit from the lower prices while patients and suppliers suffer. At a minimum, this case presents important issues regarding health care financing and provider relations that have serious consequences for patients who are the ultimate end-users of the health care system.

In fact, the Guidelines promulgated by Trigon appear to recommend that no treatment be provided in the first month of onset of acute low back problems:

> Ninety percent of patients with acute low back problems, as defined here, spontaneously recover activity tolerance within one month. The approach to a new episode in a patient with a recurrent low back problem is similar to that of a new acute episode.

App. 1094a-v. According to the RAND study, however, most patients receive an average of 5 to 18 visits to a chiropractor per episode. App. 166a. Additionally, in reviewing the literature from the Ohio State Chiropractic Association, the RAND study indicates that treatment for mild to moderate back pain should optimally occur daily to three times per week for approximately thirty days. App. 187a. Trigon's policy acts as an input reduction mechanism.

Even if the caps were not sufficient to warrant a re-examination of this case, the policy of refusing to pay a higher rate for more complex services boarders on predation. For example, Trigon's policy is to reimburse chiropractic manipulation services at one rate regardless of whether the chiropractor manipulated one region, or five regions.

There is no dispute that extra work may be required to manipulate more than one region. In fact, based upon the record, Trigon routinely reimburses additional amounts to other providers based upon the complexity and number of the procedures. The reality is that Trigon is receiving services for free. Arguably, this could be viewed by a fact-finder as evidence of predatory conduct.

The Third Amended Complaint alleges:

> Ignoring incremental RBRVS values representing the difference between treatment of the minimum number of regions of the spine and treating a greater number of regions cannot fairly or reasonably be characterized as being guided by RBRVS values or based on RBRVS methodologies. It is completely ignoring the values and methodologies.

App. 102a, ¶ 167.

There is no evidence that any savings will be passed on to consumers. As such, although the lower courts did not allow the case to go to trial, the case here has the classic signs of potential monopsony effects:

> It is tempting to infer that the lower reimbursement rate will be passed on to the patients in the form of rebates or lower insurance premiums, but this is not the case for a profit-maximizing monopsonist. The effect of monopsony power is to raise the marginal cost curve while lowering the average cost curve. n36 The former will lead to an increase in premiums if the health plan has market power in the insurance market and no change in premiums if it does not. It will not lead to a reduction in premiums because there is no economic incentive to reduce premiums, i.e., reducing premiums will not increase the insurer's profits. It is true that average cost is now lower and, therefore, the insurer could afford to lower premiums. But it would not be profit maximizing to pass on the cost savings to the policy holders. The

> reduction in average cost is what leads to an increase in profits, which provides the incentive to restrict purchases in the first place.

Blair & Herndon, 71 Antitrust L.J. at 1000.

Because of the current health care financing environment, it is important for this court to review practices which may have the effect of reducing output in the provider markets. Such reductions can have profound effects on consumers.

CONCLUSION

For the foregoing reasons, Amici submit that ACA's Petition should be granted and the decision of the Fourth Circuit Court of Appeals should be reversed.

Respectfully submitted

Jonathan B. Sprague*
Mark L. Mattioli
James Kutz
POST & SCHELL, P.C.
Four Penn Center
1600 John F. Kennedy Blvd.
Philadelphia, PA 19103
(215) 587-1155
Counsel for Amici Curiae listed in Appendix

*(counsel of record)

APPENDIX

LIST OF AMICI CURIAE

The amici chiropractic professional associations represent thousand of doctors of chiropractic from all across the nation. The amici chiropractic professional associations seek to promote chiropractic as a healing profession and to serve as spokespersons for the chiropractic profession in their respective states, districts and territories. The questions presented by this case – which go to the very survival of the chiropractic profession – are of greatest concern to all members of these amici chiropractic professional associations and, indeed, to all healthcare consumers in the United States.

The amici chiropractic professional associations include the following:

Alabama State Chiropractic Association
Alaska Chiropractic Society
Arizona Association of Chiropractic
Arkansas Chiropractic Association
California Chiropractic Association
Colorado Chiropractic Association
Congress of Chiropractic State Associations
Connecticut Chiropractic Association
District of Columbia Chiropractic Association
Florida Chiropractic Association
Georgia Chiropractic Association
Hawaii State Chiropractic Association
Idaho Association of Chiropractic Physicians
Illinois Chiropractic Society
Indiana State Chiropractice Association
Iowa Chiropractic Society
Kansas Chiropractic Association
Kentucky Association of Chiropractic
Kentucky Association of Chiropractic First District

Chiropractic Association of Louisiana
Maine Chiropractic Association
Maryland Chiropractic Association
Massachusetts Chiropractice Society
Michigan Chiropractic Society
Minnesota Chiropractice Association
Mississippi Chiropractic Association
Missouri State Chiropractors Association
Nevada Chiropractic Association
New Hampshire Chiropractic Association
Association of New Jersey Chiropractors
New Mexico Chiropractic Association
New York State Chiropractic Association
New York Chiropractic Council
North Carolina Chiropractic Association
North Dakota Chiropractic Association
Ohio State Chiropractic Association
Unified Chiropractic Association of Oklahoma
Pennsylvania Chiropractic Association
Puerto Rico Chiropractic Association
South Dakota Chiropractic Association
Tennessee Chiropractic Society
Texas Chiropractic Association
Vermont Chiropractic Association
Virgin Islands Chiropractic Association
Washington State Chiropractic Association
Wyoming Chiropractic Association

The National Community Pharmacists Association (NCPA) represents the owners, managers and employees of 25,000 independent community pharmacies across the United States. The more than 60,000 independent

pharmacists nationwide dispense a majority of the Nation's retail prescription drugs. The NCPA is committed to high-quality patient care and to restoring, maintaining, and promoting the health and well-being of the general public.

Jonathan B. Sprague*
Mark L. Mattioli
James Kutz
POST & SCHELL, P.C.
Four Penn Center
1600 John F. Kennedy Blvd.
Philadelphia, PA 19103
(215) 587-1155
Counsel for Amici Curiae listed in Appendix

*(counsel of record)

(8)

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In The
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AMERICAN CHIROPRACTIC ASSOCIATION, INCORPORATED, a non-profit corporation, *et al.*,
Petitioners,

v.

TRIGON HEALTHCARE, INCORPORATED, *et al.*,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

BRIEF *AMICUS CURIAE* OF NCMIC GROUP, INC., IN SUPPORT OF PETITIONERS

David Swinton
Counsel of Record
Nathan J. Overberg
Andrew T. Tice
AHLERS & COONEY, P.C.
100 Court Avenue, Suite 600
Des Moines, Iowa 50309-2231
(515) 243-7611

Counsel for Amicus Curiae
NCMIC GROUP, INC.

THE LEX GROUP ♦ 1108 East Main Street ♦ Suite 1400 ♦ Richmond, Virginia 23219
(804) 644-4419 ♦ (800) 856-4419 ♦ Fax: (804) 644-3660 ♦ www.thelexgroup.com

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No. 04-312

In The
Supreme Court of the United States

AMERICAN CHIROPRACTIC ASSOCIATION, INCORPORATED, a non-profit corporation, *et al.*,

Petitioners,

v.

TRIGON HEALTHCARE INCORPORATIONED, *et al.*,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF *AMICUS CURIAE* OF NCMIC GROUP, INC., IN SUPPORT OF PETITIONERS

INTEREST OF THE AMICUS CURIAE

NCMIC Group, Inc. is a diversified insurance and financial services company.[1] The company was founded in 1946 as the original provider of professional liability insurance to doctors of chiropractic. The company's

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[1] Pursuant to Supreme Court Rule 37.6, NCMIC Group, Inc. states that no counsel for a party has written this brief in whole or in part and that no person or entity, other than the NCMIC Group, Inc. has made a monetary contribution to the preparation or submission of this brief. Pursuant to Supreme Court Rule 37.2(a), the parties have provided their written consent to the timely filing of this amicus curiae brief. The written consents of the parties have been filed with the Clerk of Court pursuant to Supreme Court Rule 37.3.

flagship operation, NCMIC Insurance Company[2], insures over 35,000 doctors of chiropractic, or more than 50 percent of the profession.

As a company founded by chiropractors for chiropractors, NCMIC ("National Chiropractic Mutual Insurance Company") is a strategic partner for doctors of chiropractic. Indeed, to further advance and promote the profession, NCMIC has given more than $7 million for chiropractic research. NCMIC also sponsors business training for graduating students and malpractice risk management seminars, and has published information for all doctors of chiropractic.

This litigation raises serious questions for NCMIC Group, Inc.'s business partners, the doctors of chiropractic, and the clients they serve. Specifically, the question is whether the anti-trust laws allow the competitors of chiropractors to conspire with large health insurance companies to improperly interfere with the chiropractors' provision of effective and efficient services to their clients. If allowed, this improper interference will detrimentally impact the economic health of individual doctors of chiropractic, potentially causing them to cut costs by reducing or eliminating their professional malpractice insurance coverage, thereby directly impacting NCMIC's success as a business. In addition, if a significant number of doctors of chiropractic are unable to purchase liability coverage due to the improper interference, the pool of participating doctors of chiropractic may become actuarially insufficient to spread the risk of insurance coverage among participating doctors, making liability coverage unavailable to any doctors of chiropractic. Without the protection

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2 NCMIC Group, Inc. is a mutual holding company for NCMIC Insurance Company; NCMIC Finance Corporation (NFC); NCMIC Insurance Services (NIS); and Professional Solutions Insurance Company (PSIC).

afforded by liability coverage, patients will be unwilling to utilize doctors of chiropractic and the downward economic spiral of the profession would continue.

Similarly, NCMIC's future is tied to the growth of the profession. If competitors are able to conspire with insurance companies to deny new doctors of chiropractic a decent living, NCMIC's growth and prosperity is challenged.

In sum, NCMIC's past and future success is inextricably linked to the ability of doctors of chiropractic to compete for the provision of health care services free of any unlawful interference by their competitors.

INTRODUCTION AND SUMMARY OF ARGUMENT

The purpose of the Sherman Antitrust Act, 15 U.S.C. §§ 1-7 (2004), is to protect the public from the failure of the market. *See Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993). Thus, out of concern for the public interest, the Sherman Act directs itself against conduct which tends to destroy competition itself. *See id.* In Sherman Act § 1, 15 U.S.C. § 1, Congress took particular aim at concerted activity, because such activity is fraught with anticompetitive risk. *See Copperweld Corporation v. Independence Tube Corporation*, 467 U.S. 752, 768-69 (1984). In particular, when two independent market forces combine to act as one for their common benefit, the concerted activity suddenly increases the economic power moving in one direction, which in turn increases the potential for competition to be unfairly squelched and consumers to be deprived of a good or service which would have otherwise been supported by the market. *See id.*

In this case, the Petitioners presented evidence to the trial court that two independent market forces, a major provider of health care services (representatives of 90% of the medical doctors in Virginia) and the largest private payor for health services in Virginia (Trigon Healthcare, Inc. and its affiliated entities), engaged in concerted activity aimed at interfering with the health care consumer's ability to receive services from doctors of chiropractic. The Fourth Circuit Court of Appeals erroneously concluded that this concerted activity was not prohibited by Sherman Act § 1 because, in its view, under the intracorporate immunity doctrine the medical doctors and the health insurance companies could not conspire. *American Chiropractic Association v. Trigon Healthcare, Inc.*, 367 F.3d 212 (4th Cir. 2004).

The Fourth Circuit's decision is contrary to this Court's prior decision in *Copperweld v. Independence Tube Corp.*, 467 U.S. 752 (1984). The Fourth Circuit's decision also represents one side of a current split among the Circuit Courts on this issue. The Petition for Writ of Certiorari should be granted to reverse the Fourth Circuit's deviation from this Court's precedent, resolve the Circuit Court split on this issue, and to protect consumers and chiropractic practitioners from respondents' concerted anti-competitive conduct that violates Sherman Act § 1.

ARGUMENT: REASONS FOR GRANTING WRIT OF CERTIORARI

I. The Court Should Grant the Writ of Certiorari Because the Circuit Court's Decision is Inconsistent with this Court's Decision in *Copperweld v. Independence Tube Corp.*, 467 U.S. 752 (1984).

In the seminal antitrust case of *Copperweld v. Independence Tube Corp.*, 467 U.S. 752 (1984), this Court provided the clearest guidance to date in distinguishing

between unilateral and concerted conduct in the context of whether corporations and their related entities or bodies are capable of conspiring under Sherman Act § 1. While *Copperweld* was limited to the question of whether corporations are capable of conspiring with their wholly-owned subsidiaries, the Court clarified its prior declarations regarding the so-called "intra-enterprise conspiracy doctrine." *Id.* at 767, 772-73. This doctrine, which had been divined from prior decisions of this Court, provided that Sherman Act § 1 liability is not foreclosed merely because a parent and its subsidiary are subject to common ownership. *Id.* at 759.

In *Copperweld*, the Court established the proper analysis for determining whether a corporation is capable of conspiring with a related entity. Specifically, the Court rejected any reliance upon the form of the corporation's structure, and instead adopted a more practical test emphasizing whether a "unity of interest" *always* exists between the conspiring parties. *Id.* at 771-72. In other words, the judgment must not be based upon the "garb" in which the related entity is clothed, but rather upon the realities of the arrangement. *Id.* at 773-74 (citing *Appalachian Coals, Inc. v. United States*, 288 U.S. 344, 360 (1933)).

In this case, the Petitioners presented evidence of concerted activity between Trigon, the largest private payor for health services in Virginia, and the members of the MCAP ("Managed Care Advisory Panel"), a "panel" composed primarily of representatives of 90% of the medical doctors in Virginia. Notably, the MCAP did not include a single representative from any non-medical doctor health care profession, including doctors of chiropractic. *See* Appendix at 1095a.

Purporting to apply the principles enunciated in *Copperweld*, the Fourth Circuit found that the MCAP and Trigon were incapable of conspiring under Sherman Act § 1 as there was a unity of interest between them. *American Chiropractic Assn.*, 367 F.3d at 224-25. This finding wrongly focused upon the garb in which the MCAP was clothed, while ignoring the realities of the arrangement. In its analysis, the Fourth Circuit specifically refused to consider the MCAP members' clear and obvious underlying motivations and economic interests in limiting its query to determining the members' interests as defined by their role on the MCAP. *Id.* The court stated:

> American Chiropractic is undoubtedly correct that medical doctors and insurance companies do not, generally speaking, share a unity of interest. That, however, is not the correct inquiry in cases applying the intracorporate immunity doctrine. Instead, we look to whether the medical doctors, in their role as members of the MCAP, share a unity of interest with Trigon that makes them corporate agents of Trigon.

Id. The Fourth Circuit went on to define the parties' common interest as "addressing clinical issues in a manner that would best serve its consumers, the plan enrollees," and find that the Petitioners' claim was precluded by the intracorporate immunity doctrine. *Id.* Importantly, the Fourth Circuit completely disregarded the MCAP members' more obvious and prevailing interests in protecting their constituencies' medical practices from competition.

The Fourth Circuit's interpretation of *Copperweld* sets a dangerous precedent as it favors form over substance by relying exclusively upon the existence of an artificial structure -- the panel -- to conclude that the members of the

panel had a unity of interest with Trigon. In doing so, the Fourth Circuit ignored the teachings of this Court to look beyond form and determine whether, in reality, the entities always shared a unity of interest. Under the Fourth Circuit's analysis, parties which do not usually share a unity of interest need only apply a minimal degree of aforethought to developing an artificial structure, in this case a "panel," to avoid the proscriptions of Sherman Act § 1. This outcome could not possibly have been the intent of this Court in *Copperweld*.

It is undisputed that the profession of medical doctors, often times aided by health insurers such as Trigon, has a longstanding and well-known history of unlawfully conspiring to destroy the practice of chiropractic medicine. *American Chiropractic Assn.*, 367 F.3d at 218-19 (citing *Wilk v. American Medical Association*, 895 F.2d 352, 371 (7th Cir. 1990)); *see also* Lori B. Andrews, *The Shadow Health Care System: Regulation of Alternative Health Care Providers* , 32 Hous. L. Rev. 1273, 1288-98 (1996) (discussing barriers to the use of alternative health care providers, including doctors of chiropractic, which have been erected by their main competitors, physicians). Medical doctors have a strong self-interest, with respect to their own medical practice, in how a major health insurer formulates recommended treatment guidelines and reimbursement levels. The medical doctors' interests unmistakably differ from those of health insurance companies such as Trigon. In the present case, Trigon's interests were to minimize expenses. By contrast, the medical doctors' interests were, and undoubtedly continue to be, linked to the profitability of their own medical practice. When considering these realities, it quickly becomes clear that the interests of the MCAP's members were divergent from the interests of Trigon. There was no "unity of interest" between these parties. Thus, the members of the MCAP and Trigon were capable of conspiring in violation of Sherman Act § 1.

This Court should grant the Writ of Certiorari in order to correct the Fourth Circuit's misapplication of this Court's decision in *Copperweld*.

II. The Court Should Grant the Writ of Certiorari in Order to Address a Conflict Among the Circuit Courts with Respect to the Scope of the Intracorporate Immunity Doctrine.

Since the *Copperweld* decision, the lower courts have struggled to determine the appropriate scope of the intracorporate immunity doctrine beyond the wholly-owned subsidiary context. *See Fraser v. Major League Soccer*, 284 F.3d 47, 56-59 (1st Cir. 2002). For example, in this case the Fourth Circuit relied heavily upon its prior decision in *Oksanen v. Page Memorial Hosp.*, 945 F.2d 696 (4th Cir. 1991), in determining that Trigon could not conspire with the MCAP or its members. *See American Chiropractic Assn.*, 367 F.3d at 223-25. In *Oksanen*, the Fourth Circuit held that under the intracorporate immunity doctrine a hospital could not conspire with non-employee medical doctors serving on the hospital's peer review committee. *Oksanen*, 945 F.2d 696. The Fourth Circuit's decision in *Oksanen*, while consistent with decisions from the Third and Seventh Circuits, is contrary to decisions from the First, Sixth, Ninth, and Eleventh Circuits which have found the same parties capable of conspiring in violation of Sherman Act § 1 under certain circumstances. *Compare Id.; Weiss v. York Hospital*, 745 F.2d 786 (3rd Cir. 1984); *Pudlo v. Adamski, Jr.*, 1993 U.S. App. LEXIS 20442 (7th Cir. 1993); with *The Podiatrist Association v. LaCruz Azul de Puerto Rico*, 332 F.3d 6 (1st Cir. 2003); *Nurse Midwifery Associates v. Hibbett*, 918 F.2d 605 (6th Cir. 1990); *Oltz v. St. Peter's Community Hospital*, 861 F.2d 1440 (9th Cir. 1988); *Bolt v. Halifax Hospital Medical Center*, 891 F.2d 810 (11th Cir. 1990). This Court's guidance is needed to resolve this conflict among the circuits.

The *Bolt*, 891 F.2d 810 (11th Cir. 1990), and *Oltz*, 861 F.2d 1440 (9th Cir. 1988), decisions are representative of the circuit court decisions finding that hospitals and their medical staff (vis-à-vis hospital committees) are capable of conspiring under section 1 of the Sherman Act. In *Bolt*, the Eleventh Circuit found that a hospital's medical review board could conspire with the hospital in acting against the interests of a doctor on the medical staff. 891 F.2d 810 (11th Cir. 1990). In that case, a committee of staff doctors presented a recommendation to the hospital that it place conditions upon the doctor's appointment to the medical staff, which was accepted by the hospital. *Id.* The Court found that the hospital and its medical staff, acting by way of the peer review committee, were separate entities capable of unlawful concerted conduct. *Id.* at 819. In so finding, the Court recognized the disparate interests of the hospital and its medical staff. Indeed, the Court specifically discussed the medical staff's interest in besting its economic competition, which included other doctors on the medical staff. *Id.* at 820. As such, the *Bolt* decision tacitly recognized the dangers to market competitiveness when countervailing interests combine under the purview of a committee, and act in concert against the interests of third parties. Importantly, under these circumstances members of the medical staff were treated as separate economic actors, and not as agents of the hospital. *Id.* at 819.

In *Oltz*, the Ninth Circuit provided a more thorough analysis of the issue. 861 F.2d 1440 (9th Cir. 1988). The *Oltz* case involved allegations that a hospital conspired with its MD anesthesiologists, including by way of actions taken on a hospital committee, against a nurse anesthesiologist working within the hospital. *Id.* The Court found that while the MD anesthesiologists may have been agents of the hospital for some purposes, their interests were not so unified as to find an agency relationship for all purposes. *Id.* at 1450. The Court stated that:

> The anesthesiologists were independent contractors pursuing their personal economic interests when they pressured St. Peters to eliminate Oltz as a direct competitor. Those interests were sufficiently independent so that the collaborated conduct between the anesthesiologists and St. Peter's coalesced economic power previously directed at disparate goals.

Id. The Court found an ability to conspire despite the MD anesthesiologists' inability to act against the nurse anesthesiologist (the hospital retained sole authority to terminate). *Id.*

The Fourth Circuit's decision in this case directly contradicts and is irreconcilable with the *Bolt* and *Oltz* decisions. Specifically, in *Bolt* and *Oltz*, the courts looked at the economic realities of the committee arrangement and recognized that the non-employee medical doctors had independent competitive interests which diverged from the interests of the hospital with respect to allowing competitors access to the marketplace. Thus, the medical doctors and hospitals remained separate entities capable of concerted conduct violating Sherman Act § 1, notwithstanding the medical doctors' participation in a committee created by the hospital.

By contrast, the Fourth Circuit's decision, relying on its prior decision in *Oksanen*, 945 F.2d 696 (4th Cir. 1991), ignored the economic realities of the situation by concluding that the non-employee medical doctors instantly assumed the same interest as Trigon when they were appointed to Trigon's "panel," the MCAP, and simultaneously lost all interest in limiting their own competitors' access to the marketplace. The Fourth Circuit simply held: "Because

Trigon established the MCAP to offer input on clinical issues faced by Trigon, the individual medical doctors, in their role as members of the MCAP, share the same interest as Trigon." *American Chiropractic Assn.*, 367 F.3d at 225.

In sum, there is a split of authority among the circuits as to whether non-employees automatically assume total unification of interest with a corporation simply by agreeing to sit on a panel or committee established by that corporation such that the individuals are thereafter incapable of conspiring with the corporation against third parties. This Court should grant the Petition for Writ of Certiorari in order to fully enforce the proscriptions of Sherman Act § 1, and to eliminate the circuit courts' inconsistent application of the intracorporate immunity doctrine after *Copperweld*.

III. The Court Should Grant the Writ of Certiorari Because the Challenged Conduct Harms the Public by Unfairly Depriving the Health Care Consumer of an Effective and Efficient Treatment for a Common Ailment.

Low back pain is one of the most prevalent and costly ailments in the United States. Indeed, studies indicate that most people report low back problems at some time in their lives. *See* Appendix at 813a. National statistics indicate a general yearly prevalence of low back pain among fifteen to twenty percent of the United States population. *See id.* According to one survey among working-age people, fifty percent admit to back symptoms each year. *See id.* Back symptoms, in fact, are the most common cause of disability for persons under age forty-five. *See id.* At any given time, about one percent of the United States population is chronically disabled because of back problems, and another one percent is temporarily disabled. *See id.*

In light of its prevalence, it is not surprising that the total cost to society of low back problems is substantial. For example, low back problems are the second most common symptomatic reason expressed by patients for office visits to primary care physicians, and they are the most common reason for office visits to orthopedic surgeons, neurosurgeons, and occupational medicine physicians. *See id.* Low back problems rank third among the reasons for surgical procedures. *See id.* Moreover, although medical costs are high, loss of time from work and disability payments for work-related low back problems can together cost up to three times as much as medical treatment. *See* App. at 813a-814a. Indeed, about two percent of the United States workforce has compensable back problems each year. *See* App. at 814a. Various estimates of the total annual societal cost of back pain in the United States range from $20-$50 billion. *See id.*

Because of the magnitude of the health and economic impact of low back pain in our society, in 1994 the U.S. Department of Health and Human Services Public Health Service Agency for Health Care Policy and Research ("AHCPR") convened a 23-member multi-disciplinary private sector panel to develop a guideline for the evaluation and treatment of acute low back problems in adults. *See* App. at 808a. The panel employed explicit, science-based methods and expert clinical judgment to develop specific statements on acute low back problems in adults. *See* App. at 801a. The panel's recommendations are primarily based on the published scientific literature, but when the scientific literature was incomplete or inconsistent in a particular area, the recommendations reflect the professional judgment of panel members and consultants. *See id.* It was the panel's belief that the AHCPR-assisted clinical guidelines would make positive contributions to the quality of care in the United States. The AHCPR

encouraged practitioners and patients to use the information provided in the clinical practice guideline. *See* App. at 802a.

One of the principal conclusions reached by the AHCPR panel was that relief of discomfort can be accomplished most safely with non-prescription medication and/or spinal manipulation. *See* App. at 802a-803a. Specifically, the panel concluded that for patients with acute low back symptoms without radiculopathy the scientific evidence suggests spinal manipulation is effective in reducing pain and perhaps speeding recovery within the first month of symptoms. *See* App. at 861a. The panel defined manipulation as manual therapy in which loads are applied to the spine using short or long lever methods. *See* App. at 859a. Doctors of chiropractic provide approximately 90% of this type of spinal manipulation. *See* App. at 1040a-i.

In sum, the AHCPR panel recognized that spinal manipulation performed by doctors of chiropractic is one of the most effective and efficient treatment for one of the most prevalent and costly ailments in our society. This report, which was released in late 1994, *see* App. 1071a, was immediately recognized as a validation of the services provided by doctors of chiropractic and a potential boon to their business. *See* App. 1072a-76a.

Unwilling to allow the AHCPR panel report to freely influence the market for chiropractic services, the medical doctors on Trigon's panel adopted and endorsed low back pain treatment guidelines within months of the release of the AHCPR panel report which were inconsistent with the AHCPR's guidelines and which greatly restricted the referral of patients from primary care physicians to doctors of chiropractic in Virginia. Trigon approved these treatment guidelines and disseminated them to virtually every medical doctor in the state. In doing so, tens of thousands of

patients were improperly denied access to the most effective and efficient treatment available for their condition. *See* App. 1134a-35a. This interference not only increased the cost of treatment to the individual patients, but exacerbated the costs to society associated with their back problems. If similar conduct is allowed to go unchecked across the country, hundreds of thousands of patients will be improperly denied access to one of the most effective and efficient treatments for low back pain and the societal cost will increase exponentially.

Because seventy-five to ninety percent of health insurance coverage is purchased by employers on a group basis, consumers often do not have the ability to choose among health plans. Moreover, there is no incentive for employers to exert pressure on health plans to fairly cover alternative providers such as doctors of chiropractic. *See* Lori B. Andrews, *supra* at 1308-09. Therefore, if the health plans chosen by consumers' employers conspire with medical doctors to limit access to doctors of chiropractic, consumers will either have to pay for the alternative care out of their own pockets or consumers will be forced to acquiesce in a mode of care which is potentially less effective, more expensive, and not their first choice.

Ultimately, society as a whole is the loser with respect to healthcare costs, personal liability, and productivity losses when the best modality for each patient is not available due to improper interference with the market system by major players such as medical doctors and health insurers. As the Seventh Circuit recognized in *Wilk*, "It is anticompetitive and it raises costs to interfere with the consumer's free choice to take the product of his liking." 895 F.2d 352, 360 (7th Cir. 1990)(citing *Wilk v. American Medical Association*, 671 F. Supp. 1465, 1478-79 (N.D. Ill. 1987)). Accordingly, when two major market actors combine to place restraints on chiropractors'

competitive position in providing treatment for back pain and injury, it is to the detriment of the patients and their households, businesses and governments that pay for health insurance, businesses that suffer financial and productivity losses when workers are injured, the chiropractic profession, and thus virtually all of society. *See* App. at 1127a.

Two segments of society -- patients and employers -- are especially injured by a failure of the courts to enforce the Sherman Act § 1 with respect to the concerted efforts of medical doctors and health insurance companies to improperly interfere with the availability of alternative treatment modalities, such as chiropractic care. For example, patients incur some or all of the following impacts: higher out-of-pocket costs, treatment by types of providers not their first choice, possibly poorer treatment results, larger income losses from work absence, additional costs on family members for providing care during the extended work absences of the primary wage earners, and other impacts, psychological and social. Further, the use of less effective and more expensive treatments for back pain raises the cost of insurance for everyone, including the families or individuals who purchase their insurance themselves. *See* App. at 1126a; *see also* Rebecca Berg, *HMO Exclusion of Chiropractors*, 66 S. Cal. L. Rev. 807, 819 (1993)(recognizing that cost-comparison studies indicate that chiropractic care is a lower-cost option for numerous musculoskeletal ailments than a treatment regimen involving physicians).

Employers are hurt in at least two ways. First, employers represent the largest purchasers of health insurance and the higher insurance costs resulting from bias in favor of medical, surgical, and hospital care relative to chiropractic care are largely paid for by employers who provide group health insurance plans. Additionally, the proven superior efficacy in terms of functional mobility of chiropractic treatment of back injuries means that workers

denied care will impose on their employers higher workers' compensation costs and greater productivity losses from work absences. *See* App. at 1126a-1127a.

In light of the detrimental impact of the challenged conduct on society, this Court should review the Fourth Circuit's erroneous application of the intracorporate immunity doctrine as it applies to the concerted, anti-competitive actions of health insurers and the non-employee medical doctors serving on their panels or committees.

IV. The Court Should Grant the Writ of Certiorari Because the Challenged Conduct Harms the Public Interest by Unfairly Depriving Doctors of Chiropractic of the Level of Compensation that the Market Would Otherwise Provide.

Reductions in the number of patients seen by doctors of chiropractic due to the concerted efforts of health insurers and medical doctors necessarily result in economic loss to the excluded providers. *See* App. at 1125a. Indeed, Petitioners presented evidence to the trial court establishing that the deterred demand resulting from the erroneous guidelines developed by the medical doctors and Trigon cost Virginia chiropractors $65,492,356 over a six year period. *See* App. 1137a. This sum constituted an eleven percent reduction in total payments made to Virginia chiropractors from Trigon during the relevant period. *See id.* If similar conduct is allowed to go on unchecked across the country, the cost to doctors of chiropractic and their communities will be substantial.

If medical doctors are successful in reducing the income for doctors of chiropractic through their participation on insurance company panels, doctors of chiropractic may be forced to reduce costs or cut corners which will detrimentally affect patient care. Indeed, some doctors of chiropractic may be forced out of the profession.

Likewise, if chiropractors' income is artificially stifled by the type of concerted activity at issue in this case, students may decide that the chiropractic profession is not a viable career alternative.

If the number of doctors of chiropractic is reduced in response to this anticompetitive conduct, many patients will be denied their first choice for health care services. This result would represent a fundamental failure of the antitrust system. Antitrust scholars contend that the antitrust laws are "intended to ensure that the market place remains competitive so that worthwhile options are produced and made available to consumers, and this range of options is not to be significantly impaired or distorted by anticompetitive practices." Robert H. Lande, *Consumer Choice as the Ultimate Goal of Antitrust*, 62 U. Pitt. L. Rev. 503 (2001)(noting that the market should respond to the aggregate signals of consumer demand, not the preferences of individual businesses); *see also* Rebecca Berg, *supra* at 819 (suggesting that consumer welfare in the antitrust context recognizes that consumers should be able to choose their preferred products or services, rather than having their choices made by outsiders)(citing *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 459 (1986)).

The evidence is overwhelming that consumer demand for alternative health care services, such as chiropractic treatment, continues to rise. *See* Lori B. Andrews, *supra* at 1273-83. Consumers are seeking services from alternative providers rather than medical doctors for a variety reasons, including greater accessibility, lower costs, more personal attention, better effectiveness, and less reliance on prescription medications and therefore less exposure to the side effects associated therewith. *See, e.g.*, Lori B. Andrews, *supra* at 1276-83. If medical doctors and insurance companies are allowed to dictate whether alternative health care options remain viable going forward

irrespective of consumer demand, the anti-trust laws will have failed to fulfill one of their principal missions.

In addition, if doctors of chiropractic are forced to reduce costs or leave the profession entirely, and/or students are deterred from entering the profession in the first instance, there will be other significant, negative impacts on the broader community, such as: (1) the loss of employment for individuals working in chiropractic offices; (2) the loss of employment for individuals working at chiropractic schools; (3) the economic and social loss to a community if chiropractic schools are forced to close or consolidate; (4) the detrimental effect on the economic health of vendors to the profession, such as insurance companies, x-ray companies, table manufacturers, publications, vitamins, braces, pillows, etc.; and (5) the costs discussed in section III, supra, related to the loss of an effective and efficient health care alternative.

This Court should grant the Petition for Writ of Certiorari because of the harm to our society associated with unfairly depriving doctors of chiropractic of the level of compensation that the market would provide but for the illegal conspiracy.

CONCLUSION

For the foregoing reasons, *Amicus Curiae*, NCMIC Group, Inc., urge the Court to grant the Petition for Writ of Certiorari in order to review the Fourth Circuit's erroneous decision.

Respectfully submitted,

David Swinton*
Nathan J. Overberg
Andrew T. Tice
AHLERS & COONEY, P.C.
100 Court Avenue, Ste. 600
Des Moines, IA 50309-2231
(515) 243-7611

Counsel for Amicus Curiae
NCMIC GROUP, INC.

* (counsel of record)